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**Social cognition deficits and violence in people
with a diagnosis of schizophrenia**

Heather Langham



**Doctorate in Clinical Psychology
The University of Edinburgh**

August 2014

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1. Thesis Abstract

Introduction

It is widely reported that people with schizophrenia have social cognition deficits. In addition to their negative impact on functioning and quality of life, these deficits may also contribute to the use of violence. It has recently been established that social cognitive interventions (SCIs) can ameliorate deficits in facial affect recognition (FAR). This project aimed to systematically review whether SCIs can also improve theory of mind (ToM) abilities in people with schizophrenia. The empirical study aimed to explore whether the extent of the deficits in FAR and ToM in people with schizophrenia differed between those with and without a substantial history of violence.

Method

A systematic review was undertaken to identify studies where SCIs were provided to adults with schizophrenia or schizoaffective disorder. Key findings were highlighted with the quality of the studies' methodology and reporting assessed. A quantitative research study was also undertaken involving 22 men aged 18-64 with a diagnosis of schizophrenia or schizoaffective disorder, comparing those with and without a substantial history of violence (SHV) on measures of FAR and ToM.

Results

The majority of the 13 studies included in the systematic review found that the provision of SCIs led to significant improvements in ToM. However, all studies demonstrated a potential for bias and were limited by inadequate sample size. In the empirical study, less than half of participants scored within the normal range for *overall* FAR ability, with no difference identified between the SHV and no-SHV group. However, the SHV group were poorer at recognising sadness and showed a tendency to perform better at the detection of faux pas, compared to the no-SHV group.

Conclusions

The systematic review identified that a wide range of SCIs can improve ToM abilities in people with schizophrenia. Its findings highlight that stringent, adequately powered studies should be undertaken, utilising standardised assessments of a range of levels of ToM ability, to enable identification of the most effective intervention. The findings of the empirical study are limited by a small and imbalanced sample size between groups and so must be interpreted with caution. However, patterns observed in the results highlight areas for further exploration. The strengths of this study's design and recruitment challenges are discussed.

1.1 Acknowledgements

I would like to thank the staff members who recruited participants to the empirical study and acted as co-ordinators for each recruitment site. Without their help the study could not have been undertaken; their efforts are greatly appreciated. I would also like to thank the participants who took part in the empirical study for generously giving up their time to do so.

I would like to thank my clinical supervisor Dr Gary Macpherson for his support during this thesis, ranging from recruiting numerous participants, undertaking independent quality ratings for the systematic review and being encouraging and supportive. I would also like to thank my academic supervisors; Dr Suzanne O'Rourke for her support and expertise during the design of the thesis and Dr Nuno Ferreira who expeditiously provided very helpful comments and support when reviewing my draft articles.

I am grateful for the encouragement I have received from my family, partner and friends. In particular I would like to thank Chris for being a listening ear and putting up with my "psychology talk" from undergrad years onwards and Kirsty for being such an amazing, supportive friend throughout my doctorate.

Sadly my Grandad passed away during the doctorate and my Nanna just days before I received my final thesis approval; she would have been so proud and relieved to have learnt of this. I would like to dedicate this thesis to them as they always encouraged and wished the best for me.

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1.2 Terminology

This thesis is focused on reviewing and expanding current understanding of social cognition deficits presented by people whose range of symptomatology fits within the existing diagnostic criteria of schizophrenia or schizoaffective disorder (DSM-V, 2013). It is important to acknowledge that there is a lack of widespread agreement regarding the suitability of these diagnoses, which cover a broad range of symptomatology. An eloquent summary of such alternative viewpoints has been provided by Penn *et al.* (1997). Current clinical practice and research involves the use of these diagnostic criteria and as such this thesis makes use of these criteria to expand upon existing knowledge in this area, whilst recognising their potential limitations.

2 Systematic review

Developed for submission to The British Journal of Psychiatry (Impact Factor 6.619).

See Appendix A for author guidelines.

Exploring the effect of social cognitive interventions on theory of mind in adults with diagnoses of schizophrenia or schizoaffective disorder: A systematic review

Abstract word count: 150

Word count: 5645 (including abstract and text body; excluding title page, figures and legends, tables and legends, references and appendices).

2.1 Abstract

Introduction

Theory of mind (ToM) deficits are prevalent in people with schizophrenia and are significant predictors of community functioning and quality of life.

Aims

To establish whether social cognitive interventions (SCIs) improve ToM in people with schizophrenia, whether this is durable and which interventions are preferable.

Method

Eight databases were systematically searched to identify studies providing SCIs to adults with schizophrenia or schizoaffective disorder. Key findings were highlighted with quality of methodology and reporting assessed.

Results

Most studies reported significant improvements in ToM, in some cases with large effect sizes, however durability was not reported. All studies had potential for bias and were limited by inadequate sample size.

Conclusions

This review identifies a promising area for further development. Stringent, adequately powered studies should be undertaken utilising standardised assessments of a range of levels of ToM ability to enable identification of the most effective intervention.

Declaration of Interest

None.

2.2 Introduction

2.2.1 *Social cognition deficits in schizophrenia*

It is widely reported that people with schizophrenia have cognitive deficits^{1, 2}. These include difficulties with social cognition, such as being able to accurately recognise facial expressions of emotion³, with reported poorer performance in theory of mind tasks^{4, 5}. Such social cognition deficits are of great relevance when considering the impact of schizophrenia on social functioning; a meta-analysis of studies involving people with non-affective psychosis found that social cognition has a stronger association with social functioning than neurocognition⁶. A recent meta-analysis confirmed that social cognitive interventions are effective at improving facial affect recognition abilities in people with schizophrenia⁷. It therefore seems prudent to build upon this and explore whether it is also possible to improve theory of mind abilities through the provision of social cognitive interventions.

2.2.2 *Current theoretical understanding of theory of mind and its development*

Theory of mind has been described as *'being able to infer the full range of mental states (beliefs, desires, intentions, imagination, emotions, etc.) that cause action. In brief, having a theory of mind is to be able to reflect on the contents of one's own and other's minds'*⁸.

Development of this ability normally occurs during childhood, with an ability to infer other's mental states in more complex situations demonstrated at an older age than for more straightforward situations⁹⁻¹¹.

There are different theories about how theory of mind develops. One theory proposes that this development is innate¹², while another suggests that individuals simulate how they would feel in a situation to help them identify how others may feel¹³. Alternative theories are that the development of executive functioning enables

greater inhibition of one's own perspective to enable consideration of another's experience¹⁴ or that children form and refine mental concepts of the world and others through experience¹⁵. However, there has traditionally been a gap between theories of the development of these abilities and the focus of social neuroscience studies, which tend to be directed at identifying the location of these abilities¹⁶. This has meant that current neuroimaging evidence does not fully support one theory in exclusion to another. Greater integration of these areas in future research would enable a more cohesive understanding of what may disrupt the development of theory of mind abilities along with a clearer understanding of the effect of interventions aimed to alleviate theory of mind deficits.

The complete development of theory of mind is important, as theory of mind abilities have been identified as a strong predictor of community social functioning¹⁷ and indeed to be the specific component within social cognition that significantly contributes to this prediction¹⁸. Theory of mind abilities in people with schizophrenia have also been shown to have a significant correlation with introspective and interpersonal aspects of quality of life¹⁹. Given the relationship of theory of mind with such important areas, identification of any effective interventions to improve these is clearly required.

2.2.3 Improving theory of mind deficits in schizophrenia

There have been conflicting findings arising from studies exploring the theory of mind abilities of people with schizophrenia prescribed with first or second generation antipsychotic medication^{20, 21} and the reliability of such studies has been undermined by inadequate power and a lack of randomisation²². Therefore, identification of alternative approaches not requiring a potentially unfavourable change to one's prescribed medication is desirable.

One meta-analysis into the effect of social cognitive training for schizophrenia²³ reported small to moderate effects of training on improving theory of mind abilities, however the scope of interventions identified was limited by the broader aims of the meta-analysis. Studies where social cognitive training was not provided in combination with training in neuro-cognition were not included. Additionally, many studies in this field have since been published. This review was therefore undertaken to systematically identify all studies measuring change in theory of mind abilities in people with schizophrenia or schizoaffective disorder as a result of the use of any social cognitive intervention.

2.3 Aims

The main aims of this systematic review were to establish:

- a) Do social cognitive interventions improve theory of mind abilities in adults with diagnoses of schizophrenia or schizoaffective disorder?
- b) Where reported, are any changes still observed at follow up?
- c) Are certain interventions preferable, when considering the extent of improvement in theory of mind abilities, along with the resources required for their delivery?

2.4 Methods

This review was developed following the PRISMA statement for systematic reviews^{24, 25}.

2.4.1 Study selection

For inclusion in this review, studies had to meet all of the following criteria:

i) Participants

All participants were adults (aged 18 or over) with a diagnosis of schizophrenia or schizoaffective disorder.

ii) Interventions

Studies were included where they used a non-pharmacological intervention targeting one or more of the areas of social cognition (theory of mind, social perception/knowledge, attributional bias and emotional processing), as defined by the NIMH consensus-building meeting²⁶.

iii) Comparisons

Due to this being a relatively new area, studies with or without a comparison or control group were included. However, the design of studies was considered via review of the methodological quality of the study.

iv) Outcomes

Change in theory of mind abilities was assessed pre- and post- intervention, using at least one theory of mind measure.

v) Study design

All studies were to be intervention studies; due to this being a relatively recent field both randomised and non-randomised studies were included.

vi) Additional criteria

Only studies where a full journal article (i.e. not just abstracts or conference presentations) available to the reviewer (who had NHS and University access to publications) in the English language were included.

2.4.2 *Search strategy*

Stage 1: The databases MEDLINE, EMBASE, PsycINFO, The Cochrane Library, Cumulative Index to Nursing and Allied Health Literature Plus (CINAHL Plus), International Bibliography of the Social Sciences (IBSS), Scopus and ProQuest Dissertations and Theses were searched using the following strategy: 'schiz*' AND "theory of mind" AND ['remed*' OR 'rehab*' OR 'train*' OR 'mentali*' OR 'interven*']. This search covered all publications from inception of these databases until 1st June 2014 (25th June 2014 in the case of ProQuest Dissertations and Theses).

Stage 2: Initially, the titles and abstracts of the articles were screened; studies that clearly did not fulfil one or more of the inclusion criteria were filtered out. However, where studies involved people with diagnoses with similarities to the inclusion criteria (e.g. schizophrenia-spectrum or psychosis), these were initially included for further review. This approach was taken as it was noted that some studies used a broader term in their title but only included participants meeting the inclusion criteria.

It was decided that any systematic reviews and meta-analyses identified that included studies addressing the inclusion criteria would also be retained separately for hand-searching.

Stage 3: Duplicates of the remaining studies were removed. Hand-searching of studies included in any relevant systematic reviews and meta-analyses identified was undertaken with the aim of including any novel studies meeting the review's inclusion criteria.

Stage 4: The methods sections of the remaining studies were then reviewed; only those where all the inclusion criteria were met were retained for inclusion.

2.4.3 *Descriptive synthesis*

Pertinent details regarding each of the studies, including authors, publication date, diagnoses of participants, intervention(s) used, theory of mind outcome measure(s) utilised and key findings relevant to theory of mind were extracted. This enabled consideration of both their findings and each study's strengths and potential biases, as identified by the following quality assessment process.

2.4.4 *Quality assessment*

The two quality assessment tools reported to be most suitable for this field and appropriate for reviewing both randomised controlled trials and non-randomised studies²⁷ were not considered to be fully appropriate for the purpose of this review. These either did not allow a sufficiently broad range of rating to differentiate between the effectiveness with which areas of importance had been addressed²⁸ or ascribed 'moderate' ratings when areas had either been partially addressed or not described²⁹. Therefore neither tool allowed the quality of control of potential biases to be fully differentiated between studies. Additionally, as not all studies included were primarily targeting improvement in theory of mind, for the purposes of this review it was considered more appropriate to assess the quality of the study in relation to this outcome rather than the quality of all tools and analyses undertaken as a whole.

Bespoke quality criteria and ratings were therefore developed by the lead author (HL) to address the areas pertinent to this review, with reference to existing bespoke criteria developed for use in other systematic reviews^{30, 31}. The criteria used were devised to cover the areas recommended for inclusion by the Centre for Reviews and Dissemination³², which are '*Appropriateness of study design to the research objective, risk of bias, other issues related to study quality, choice of outcome measure, statistical issues, quality of reporting, quality of the intervention and generalisability.*' For each area

rated, the criteria aimed to assess how effectively the study had addressed that area to reduce its potential impact on the reliability of the study's findings. In addition to differentiating if an area was 'well addressed' or 'adequately addressed', the rating criteria included 'limited' if an area had been inadequately addressed, 'not addressed' where a quality area had not been addressed by the study and 'not reported' if it was not clear from the study whether an area had been addressed or not. The requirements for each level of rating were selected to be relevant to the aims of the review and to differentiate between existing studies, rather than comparison to an 'ideal'. The full rating criteria used are outlined in Appendix B.

2.4.5 Inter-rater reliability of quality assessment ratings

All studies were rated by the first author (HL) using this quality assessment criteria, with seven (54%) independently reviewed using the same quality assessment criteria by the second author (GM). In order to calculate inter-rater reliability, ratings of 'well addressed' were assigned a score of 2, 'adequately addressed' scored as 1 and 'limited', 'not addressed' and 'not addressed' coded as 0. The percentage agreement between raters for the points awarded on each area assessed for each study was calculated. Inter-rater reliability was assessed by calculating the level of agreement between raters, using a weighted kappa statistic given the ordinal nature of this coding³³. Where ratings differed by more than 1 point, this was resolved through re-reviewing the criteria and relevant papers, identifying why the discrepancy occurred and discussing which rating would be more appropriate.

However, this scoring procedure was not used to determine an overall rating of the study's quality. As noted by the Cochrane Collaboration³⁴, assigning numerical ratings to each area can be problematic as this implies that each point is of a similar importance in removing/reducing bias in a study. Instead, the descriptive ratings of each area assessed were displayed in an overall summary table to allow an overview of each study's relative strengths and limitations.

2.5 Results

Application of the first stage of the above search strategy identified a total of 813 results from the eight databases searched (see Figure 2.1). Following stages 2 and 3 of the search strategy previously outlined, 25 papers were retained for further consideration. During stage 4, each study's methodology and results were further reviewed, with a further 12 papers excluded. The reasons for their exclusion are presented in Appendix C.

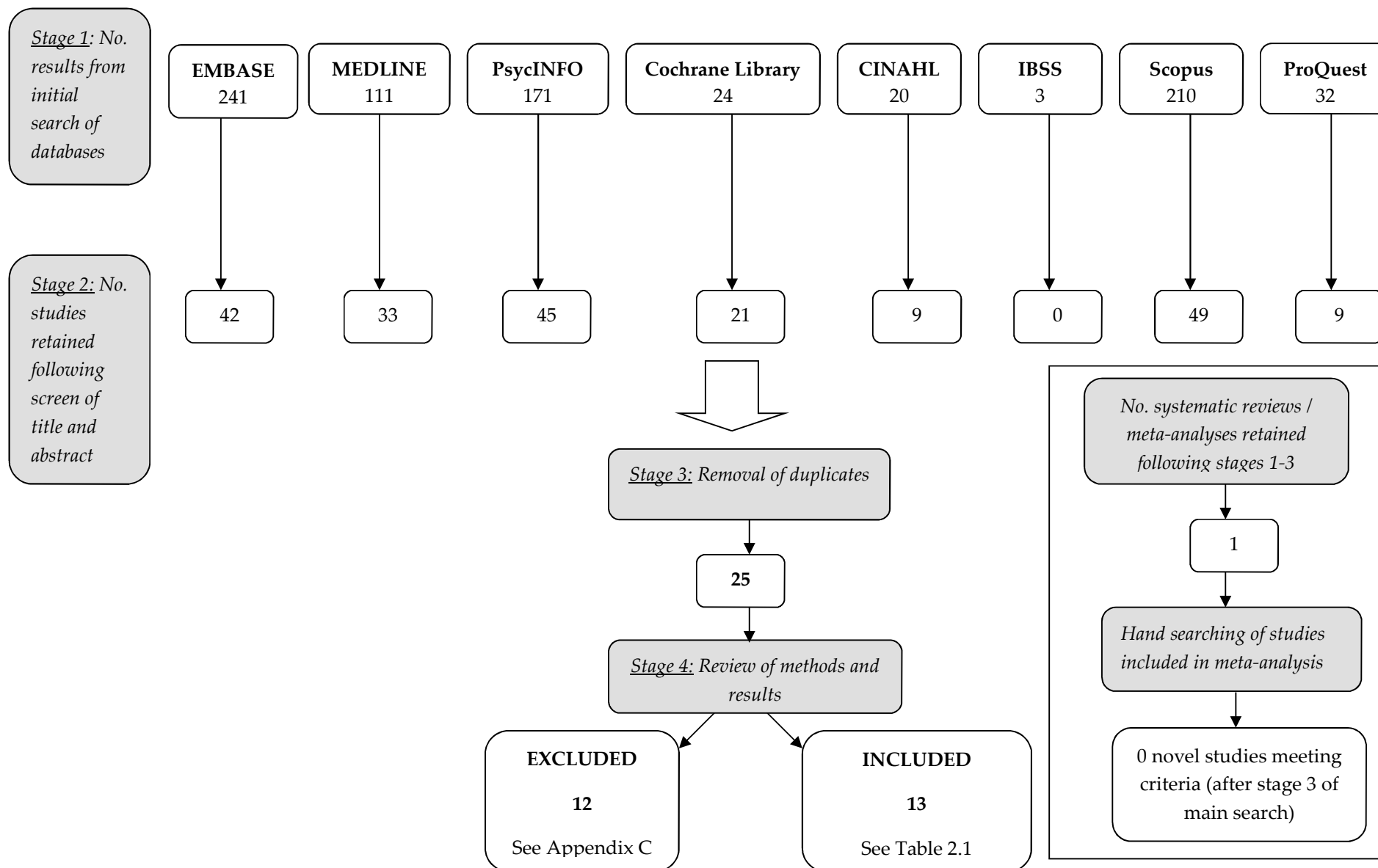


Figure 2.1. Flowchart of systematic review search process

2.5.1 *Characteristics of studies included in review*

i) Participants

Table 2.1 summarises the characteristics of the studies included in the review, along with their findings relevant to theory of mind. Eight studies (62%) only included participants meeting diagnostic criteria for schizophrenia, whilst the remaining five involved participants meeting diagnostic criteria for schizophrenia or schizoaffective disorder. Nine (69%) studies included out-patients, two used in-patients and two used a mix of in-patients and out-patients. In one of the studies, most participants were receiving input from services for veterans³⁵.

ii) Interventions

A wide range of interventions were utilised in the studies. These included Social Cognition and Interaction Training³⁶⁻³⁸, Metacognitive and Social Cognition Training³⁹ and Emotion and Theory of Mind Imitation Training⁴⁰. Additionally, Training of Affect Recognition⁴¹, Cognitive-Emotional Rehabilitation⁴² and Mental-State Reasoning Training for Social Cognitive Impairment⁴³ were used. A variety of other interventions including Integrative Psychological Therapy⁴⁴, interventions involving discussion of interpersonal scenes in films^{44, 45} and other group social cognitive and/or rehabilitative interventions^{35, 46, 47} were also used. A summary of what each of these interventions entailed is provided in Table 2.1. Only one of these interventions was provided on an individual basis⁴⁵ with the rest delivered in groups of at least two participants. The duration of intervention ranged from two one-hour sessions⁴⁵ to a total of 24 sessions⁴⁰.

iii) Comparisons

All but one study⁴³ used a control or comparison group. 'Treatment as usual' – generally antipsychotic medication and the use of other services – was utilised as a control in seven studies^{36-39, 44, 45, 47}. Comparisons used included an active control in the form of a newspaper discussion group⁴⁶ or alternative interventions that were

not aimed at social-cognition abilities, such as Problem Solving Training^{40, 42} or Cognitive Remediation Training⁴¹.

iv) Outcome Measures

A wide range of outcome measures were used, generally with a focus on cognitive theory of mind skills, apart from one study where only affective theory of mind ability was assessed³⁸.

v) Study Design

Eight (61.5%) of the studies reported that random allocation was undertaken for each of their treatment arms; in two studies this was undertaken independently to ensure concealment of this procedure^{40, 42}.

Table 2.1. Key characteristics and findings of studies included in review

Study	Participants' demographics; number recruited	Intervention(s); number of participants completing intervention and attrition (where reported)	Control; number of participants completing control and attrition (where reported)	Theory of Mind outcome measure(s); reported timescale of assessments	Key Theory of Mind findings
Bechi <i>et al.</i> (2012) ⁴⁴	Out-patients with schizophrenia (DSM IV-R) (n=76)	<ul style="list-style-type: none"> Video-based social cognitive treatment (SCT):- <ul style="list-style-type: none"> Video-based social cognitive training (VST), and Within last 6 months had started Cognitive Remediation Therapy (CRT) (2 x 1-hour individual sessions per week) <p><i>VST involved showing film clips of social interactions and guiding discussion of interpretations regarding characters' emotions, relationships, implicit motivations and mental states.</i></p> <p>(n=27 completing, 3.6% attrition)</p> <ul style="list-style-type: none"> Standard Rehabilitation Treatment (SRT):- 	<ul style="list-style-type: none"> 'Time-matched control group (NT) - visited every two weeks through a routine check with the psychiatrist'. <p>(n=22 completing, 8.3% attrition)</p>	<ul style="list-style-type: none"> Theory of Mind Picture Sequencing Task (PST)⁴⁸ Theory of Mind Questionnaire (linked to PST). <p>T0 = pre intervention</p> <p>T1 = 3 months after T0</p>	<p>There was a significant improvement within the SCT group's performance on the PST questionnaire, First and Second Order false beliefs and PST Cheating detection. These improvements had medium to large effect sizes. No significant change was found on Third order false belief or PST sequencing scores within the SCT group.</p> <p>There were no significant within-group changes in theory of mind (ToM) scores for the SRT and NT groups.</p> <p>Medium to large effect sizes were reported for between-group improvement of PST</p>

		<ul style="list-style-type: none"> - 'Integrated Psychological Therapy social cognitive training (IPT)' (1-hour group session for 3 months). <p><i>and</i></p> <ul style="list-style-type: none"> - Within last 6 months had started Cognitive Remediation Therapy (CRT) (2x 1-hour individual sessions per week) <p><i>SRT focused on 'verbal communication, social skill training and problem solving'.</i></p> <p><i>(n=24, 63% male, no attrition)</i></p> <p><i>CRT consisted of computer-aided exercises that were tailored to participant's baseline neuropsychological assessment.</i></p>			Questionnaire, First and Second order false beliefs and Cheating detection scores, in favour of SCT when compared to SRT.
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Bechi <i>et al.</i> (2013) ⁴⁶	<p>Out-patients with schizophrenia (DSM IV-R)</p> <p>(n=30)</p>	<ul style="list-style-type: none"> • ‘Theory of Mind Intervention’ group (TOMI) (2 x 1-hour group sessions per week, total of 18 sessions) <p><i>This involved three modules focusing on cognitive ToM, using guided discussion of comic strip scenarios. This was then followed by two modules regarding affective ToM, involving guided study of faux-pas stories and appreciation of irony tasks.</i></p> <p><i>and</i></p> <ul style="list-style-type: none"> • Cognitive Remediation Therapy (3 x 1-hour individual sessions per week using Cogpack Software⁴⁹, for 12 weeks – within last 6 months). <p><i>(n=19, no attrition reported)</i></p>	<ul style="list-style-type: none"> • Newspaper discussion group (ACG) (2 x 1-hour group sessions per week, total of 18 sessions) <p><i>Reading and discussing articles regarding recent political and regional issues, with goal of reducing speech blockage and communication difficulties.</i></p> <p><i>and</i></p> <ul style="list-style-type: none"> • Cognitive Remediation Therapy (3 x 1-hour individual sessions per week using Cogpack Software⁴⁹, for 12 weeks – within last 6 months). <p><i>(n=11, no attrition reported)</i></p>	<ul style="list-style-type: none"> • Theory of Mind Picture Sequencing Task (PST)⁴⁸ • Theory of Mind Questionnaire (linked to PST). <p>T0 = baseline - pre intervention</p> <p>T1 = 3 months after T0</p>	<p>Within the TOMI group there was a significant improvement in the PST total score, Second order false beliefs total score and total sequencing scores (all medium to large effect sizes).</p> <p>There was a significant post-intervention improvement in the PST total score and Second order false beliefs score for TOMI as compared to the ACG group.</p> <p>No significant interactions were found when comparing the two groups on Third order false belief scores or sequencing scores.</p>
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Horan <i>et al.</i> (2009) ³⁵	<p>Out-patients, predominantly also receiving input from Veterans Administration services, with schizophrenia or schizoaffective disorder (DSM-IV)</p> <p>(n=34)</p>	<ul style="list-style-type: none"> Social Cognitive intervention (2 x 1-hour group sessions per week, total of 12 sessions) <p><i>Consisted of two phases of six sessions each:</i></p> <ol style="list-style-type: none"> 1) Emotion and social perception 2) Social attribution and Theory of Mind <p>(n=15 completing, 11.8% attrition)</p>	<ul style="list-style-type: none"> 'Illness self-management and relapse prevention skills' (2 x 1-hour group sessions per week, total of 12 sessions) <p><i>'Modified version of the Symptom Management Module of the UCLA Social and Independent Living Skills Program^{50, 51}. This is a structured, fully manualized training program.'</i></p> <p>(n=16 completing, 5.9% attrition)</p>	<ul style="list-style-type: none"> The Awareness of Social Inference Test (TASIT)⁵² – Part 3 <p>T0 = pre assessment</p> <p>T1 = post assessment</p>	<p>There were no significant within- or between-group changes in scores on the TASIT for either the intervention or control group.</p>
Kayser <i>et al.</i> (2006) ⁴⁵	<p>Out-patients and one participant close to leaving hospital, with schizophrenia⁵³</p> <p>(n=14)</p>	<p>Guided analysis of social interactions shown in scenes from films (1-hour individual session per week, total of 2 sessions)</p> <p><i>Discussion of interpretations of characters' behaviour and mental state</i></p> <p>(n=8, no attrition)</p>	<p>'Usual consultations with their psychiatrists - no training sessions between the two clinical evaluations'.</p> <p>(n=6, no attrition)</p>	<ul style="list-style-type: none"> ToM task without language⁵⁴ <p>T0 = baseline – before 1st training session.</p> <p>T1 = one week later, after 2nd training session.</p>	<p>No significant difference on score on ToM task was found between groups as a result of intervention received. However, intragroup paired comparisons for each participant found those in the intervention group showed a significant reduction in errors made; this was not the case for the control group.</p>

Kleinlein (2010) ³⁶	<p>Out-patients with schizophrenia or schizoaffective disorder⁵³</p> <p>(n=40)</p>	<ul style="list-style-type: none"> • Social Cognition and Interaction Training (SCIT)⁵⁵ (up to 3 x 1-hour group sessions per week, total of 20 sessions) <p><i>'Manual-based treatment approach' addressing social cognitive dysfunctions; consists of three phases:</i></p> <ol style="list-style-type: none"> 1) <i>'Understanding emotions</i> 2) <i>Exploring social cognitive biases'</i> 3) <i>Applying materials and skills into participants' everyday lives</i> <p><i>and then</i></p> <ul style="list-style-type: none"> • Treatment as Usual (TAU) (see right) <p><i>(n=18 completing interventions, 10% attrition – but overall there was 22.5% and 35% attrition for completing assessments at T1 and T2 respectively).</i></p>	<ul style="list-style-type: none"> • Treatment as Usual (TAU) <p><i>'Participants...continued to receive their individual standard care regimen typically consisting of medication management, case management and a range of occupational, rehabilitational and supportive services'.</i></p> <p><i>and then</i></p> <ul style="list-style-type: none"> • Social Cognition and Interaction Training (SCIT) (see left) <p><i>(n=18 completing interventions, 10% attrition – but overall there was 22.5% and 35% attrition for completing assessments at T1 and T2 respectively).</i></p>	<ul style="list-style-type: none"> • Hinting task⁵⁶ <p>T0 = pre interventions</p> <p>T1 = post first intervention</p> <p>T2 = post both interventions</p>	<p>Within-group improvements on the Hinting task were not significant.</p> <p>There was no significant between-group difference at T1 (or T2).</p>
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Marsh <i>et al.</i> (2013) ⁴³	<p>In-patients and out-patients with schizophrenia or schizoaffective disorder</p> <p>(n=17; of which 8 in-patients, 6 out-patients)</p>	<ul style="list-style-type: none"> Mental-State Reasoning Training for Social Cognitive Impairment (SoCog-MSRT) (2 x 1-hour group sessions per week, total 10 sessions) <p><i>'Manually-driven suite of activities including games and short films...all activities centred on vignettes of social situations with a focus on making inferences and predictions about different characters' thoughts, feelings and behaviours.'</i></p> <p>(n=14 completing, 17.6% attrition)</p>	<ul style="list-style-type: none"> No control. 	<ul style="list-style-type: none"> Hinting task⁵⁶ Reading the Eyes in the Eyes (RMET)⁵⁷ False-Belief Picture Sequencing Test (FBPST) – using Picture Sequencing Test for False Belief (PST-FB) (i.e. social story) and PST for Mechanical Control (PST-MC) (i.e. non-social story)^{5, 58} <p>T0 = baseline</p> <p>T1 = post-training</p>	<p>There was a significant within-group improvement after training in SoCog-MSRT in scores on PST-FB, PST-MC and RMET.</p> <p>No significant change was found on the Hinting task.</p>
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Mazza <i>et al.</i> (2010) ⁴⁰	<p>Out-patients with schizophrenia⁵⁹</p> <p>(n=33)</p>	<ul style="list-style-type: none"> Emotion and Theory of Mind Imitation Training (ETIT) (2 x 50 minute group sessions, for 12 weeks). <p><i>Aimed to improve social cognition processes. Involves four phases:</i></p> <ol style="list-style-type: none"> 1) 'Observing eye directions and learning to interpret intentions through others' eye gaze direction 2) Observing, imitating and identifying facial emotion expressions 3) Inferring mental state of characters shown in sketches 4) Attribution of intentions through observation of characters' actions as shown in comic sketches' <p>(n=16 completing, no attrition)</p>	<ul style="list-style-type: none"> Problem Solving Skill Training (PST)^{60, 61}. (2 x 50 minute group sessions, for 12 weeks). <p><i>Aims to teach participants strategies to solve problems by evaluating their own and others' actions. Involves four phases:</i></p> <ol style="list-style-type: none"> 1) Identification of personal life goals and problems they need to overcome to achieve these. Informed about six-step problem solving method; this is then used for a practical problem. 2) Application of problem solving method to an interpersonal problem. 3) Application of method and use of problem analysis to address residual psychotic and non-psychotic symptoms 4) Addresses coping with distressing feelings. <p>(n=17 completing, no attrition)</p>	<ul style="list-style-type: none"> Advanced Theory of Mind Scale – 'Italian adaptation of a cognitive task'⁶². First and second order false belief stories - The Washing Machine Story and the Wallpaper Story⁶³. <p>T0 = baseline</p> <p>T1 = 3 months after T0</p>	<p>First order false belief story scores improved after ETIT intervention.</p> <p>There was a significant group x time interaction for the scores on the second-order false belief story and Advanced ToM scale for the ETIT group only.</p>
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Roberts & Penn (2009) ³⁷	<p>Out-patients with schizophrenia and schizoaffective disorder⁵³</p> <p>(n=31)</p>	<ul style="list-style-type: none"> • Social Cognition and Interaction Training (SCIT)⁶⁴ (20 week group intervention) <p><i>Manualised treatment aiming to improve social cognition, consisting of three phases:</i></p> <ol style="list-style-type: none"> 1) <i>Addressing emotion perception dysfunction</i> 2) <i>Addressing attributional biases and ToM dysfunction</i> 3) <i>Practicing applying skills learnt to interpersonal problems in their own lives</i> <p><i>along with</i></p> <ul style="list-style-type: none"> • Treatment as Usual (TAU) – see right <p>(n=14 completing, 30% attrition)</p>	<ul style="list-style-type: none"> • Treatment as usual (TAU) <p><i>‘Comprised a suite of available services, including medication management, individual and group psychotherapy, case management, family education and support, and occupational therapy. Use of TAU services differed across participants based on collaborative planning between clients and their clinicians...No TAU participants received social-cognitively oriented treatment during the study period; several received individual, symptom-focused cognitive behavioural treatment’.</i></p> <p>(n=11, no attrition)</p>	<ul style="list-style-type: none"> • Hinting Task⁵⁶ • The Awareness of Social Inference Task (TASIT) – abbreviated (used fewer items). This measure was introduced for use with the second cohort onwards. <p>T0 = baseline</p> <p>T1 = post-intervention</p>	<p>The improvement observed on the TASIT-abbreviated scores, for those classed as ‘completers’ of the intervention group, corresponded to a moderate effect size and ‘approached trend level’ significance. No change was found in the Hinting task scores.</p>
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Rocha & Queirós (2013) ³⁹	Out-patients with schizophrenia ⁵³ (n=35)	<ul style="list-style-type: none"> Metacognitive and Social Cognition Training (MSCT) (10 weeks of group training, total of 18 sessions) <p><i>Consists of metacognitive psycho-education, along with interactive social cognition remediation exercises plus didactic teaching materials to teach social cognitive strategies. The latter were developed by authors or based on well-known training programs.</i></p> <p>(n=19)</p>	<ul style="list-style-type: none"> Treatment as usual (TAU) <p><i>Regular medication and psycho-social services as depending on own rehabilitation plan, including 'life and social skills training, psycho-educational groups, leisure activity suggestions, stress management, family education and support, and individual psychotherapy'.</i></p> <p>(n=16)</p>	<ul style="list-style-type: none"> Hinting Task⁵⁶ <p>T0 = baseline</p> <p>T1 = Up to 2 weeks after training</p>	Scores on the Hinting task of those completing MCST were significantly better than those receiving TAU. There was a large within-group effect size for pre to post scores change. The between-group effect size was small.
Roncone <i>et al.</i> (2004) ⁴⁷	In-patients with schizophrenia, residual type (295.60) ⁵³ (n=20)	<ul style="list-style-type: none"> Rehabilitation program (up to one hour group session per week, for 22 weeks) <p><i>Covered areas aimed to increase participants' ability to change incorrect beliefs and their thinking strategies. These included modifying beliefs, recognising emotions, communicating feelings and use of role play.</i> (n=10)</p>	<ul style="list-style-type: none"> 'Antipsychotic medication and supportive psychotherapy when necessary.' <p>(n=10)</p>	<ul style="list-style-type: none"> 'Theory of mind stories.'- assessing 1st and 2nd order false beliefs <p>T0 = baseline</p> <p>T1 = 6 months after baseline</p>	Significant improvement in both 1 st and 2 nd order false belief scores for group receiving intervention.

Veltro <i>et al.</i> (2011) ⁴²	Out-patients with schizophrenia ⁵⁹ (n=24)	<ul style="list-style-type: none"> • Cognitive-Emotional Rehabilitation (REC). (75-90 minute group session per week, for 6 months). <p><i>Structured, manualised intervention using psycho-education and CBT techniques. Similar to an approach previously used⁶⁵.</i></p> <p>(n=12)</p>	<ul style="list-style-type: none"> • Problem Solving Training (PST) (90 minute weekly group session, with two exercises between each session, for six months). <p><i>Aims to teach participants strategies to solve problems by evaluating their own and others' actions. Follows manual by Fallon (unpublished), similar to a published manual⁶⁰. Involves four phases:</i></p> <ol style="list-style-type: none"> 1) <i>Identification of personal life goals and problems they need to overcome to achieve these. Informed about six-step problem solving method; this is then used for a practical problem.</i> 2) <i>Focuses on interpersonal problems.</i> 3) <i>Addresses 'residual psychotic and non-psychotic symptoms'</i> 4) <i>Addresses coping with distressing feelings.</i> <p>(n=12)</p>	<ul style="list-style-type: none"> • Advanced Theory of Mind Scale – this was an Italian adaptation of a cognitive task⁶² • First and second order false belief stories - The Washing Machine Story and the Wallpaper Story⁶³. <p>T0 = baseline T1 = 12 months</p>	<p>The group receiving the REC showed a significant improvement in their first order Theory of Mind scores. Neither group showed significant improvement in their second order Theory of Mind score.</p> <p>The scores on the Advanced Theory of Mind Scale were not reported.</p>
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Wang <i>et al.</i> (2013) ³⁸	<p>Out-patients with schizophrenia⁵³</p> <p>(n=43)</p>	<ul style="list-style-type: none"> SCIT (Chinese translation) (group intervention, for 20 weeks) <p><i>Translated SCIT manual into Chinese and remade materials using Chinese actors. Covered three phases:</i></p> <ol style="list-style-type: none"> 1) <i>Emotion perception training</i> 2) <i>Theory of mind and attributional style</i> 3) <i>Integration</i> <p>and</p> <ul style="list-style-type: none"> Treatment as usual (TAU) – see right (n=22) 	<ul style="list-style-type: none"> TAU – antipsychotic medication <p>(n=17, 19% attrition)</p>	<ul style="list-style-type: none"> Computer administered Chinese version of the Eyes task. <p>T0 = 1 week prior to intervention</p> <p>T1 = 6 months after the end of the 20 week program</p>	<p>Significant improvement in performance of group receiving SCIT. There was a large within-group effect size for this improvement along with a large between-group effect size.</p>
Wolwer & Frommann (2011) ⁴¹	<p>In-patients with schizophrenia or schizoaffective psychosis (which falls within schizoaffective disorder)⁶⁶</p> <p>(n=38)</p>	<ul style="list-style-type: none"> Training of affect recognition (TAR)⁶⁷ (2 x 45-60 minute program held in small groups, for 6 weeks) <p><i>'Manualised, computer aided...program that...targets improvements in facial affect recognition'.</i></p> <p>(n=15, 25% attrition)</p>	<ul style="list-style-type: none"> Cognitive remediation training (CRT) 2 x 45-60 minute program held in small groups, for 6 weeks) <p><i>'Targets neurocognitive impairments in attention, memory and executive functions without addressing any kind of social cognition'. Involves computer and desk work.</i></p> <p>(n=15, 16.7% attrition)</p>	<ul style="list-style-type: none"> Theory of Mind Picture Sequencing Task (PST)⁴⁸. Theory of Mind Questionnaire (linked to PST). <p>T0 = pre-treatment T1 = post-treatment</p>	<p>Only the TAR group showed a significant improvement in the ToM score. There was a large effect size for the between-group difference of TAR vs CRT.</p>

2.5.2 *Outcomes of interventions*

The outcomes of the interventions used in each study are detailed in Table 2.1. The majority of studies (85%) did find significant improvements on at least one of the Theory of Mind measures used. A variety of interventions were used in the studies where significant improvements were observed: group video-based social cognitive treatment combined with individual computerised cognitive remediation therapy (CCRT)⁴⁴; a 'theory of mind intervention group' addressing both cognitive and affective theory of mind combined with individual CCRT⁴⁶; group-based Social Cognition and Interaction Training³⁸; Mental-State Reasoning Training for Social Cognitive Impairment group sessions⁴³; Emotion and Theory of Mind Imitation Training group⁴⁰; Metacognitive and Social Cognition Training group³⁹; group rehabilitation program targeting unhelpful beliefs and emotion recognition⁴⁷; Cognitive-Emotional rehabilitation group⁴² and group-based Training of Affect Recognition⁴¹. A summary of each of these interventions is provided in Table 2.1.

It was not possible to determine whether these improvements were durable, as eleven (85%) of the studies only assessed theory of mind abilities pre- and post-intervention and did not report any follow-up assessment. A further two studies did not assess theory of mind abilities directly after training, but instead assessed this six months later^{38, 42}.

The theory of mind areas where improvement occurred involved a range of measures which mainly focused on cognitive abilities, but affective theory of mind was assessed in two studies^{38, 43}. The lack of consistency in reporting along with the variability of measures used meant it was not possible to identify whether one intervention was clearly preferable to another in terms of size of theory of mind improvement achieved. The length of interventions where improvements were achieved ranged from two sessions⁴⁵ up to six months⁴².

2.5.3 *Inter-rater reliability for quality assessment ratings*

The inter-rater reliability of the independent quality assessment ratings, as calculated using weighted kappa³³ fell in the 'moderate' range ($K_w=0.42$)⁶⁸. The percentage of exact agreement between raters was 55%. Where ratings differed by more than one point (6%), these were then discussed and resolved. Table 2.2 shows the ratings assigned by the primary rater (HL), including one rating which was modified following the above process.

Table 2.2. Quality assessment ratings of studies included in the review.

Study	Random- isation	Blinding	Attrition	Attendance	Training & Monitoring	Intervention replicability	Internal validity – other	External validity	Outcome measure	Power/ sample size	Analysis (and reporting)	Reporting
Bechi <i>et al</i> (2012) ⁴⁴	L	L	AA	NR	NR	AA	AA	AA	WA	NR	WA	AA
Bechi <i>et al</i> (2013) ⁴⁶	AA	WA	NR	NA	NR	AA	WA	WA	WA	L	WA	AA
Horan <i>et al</i> (2009) ³⁵	AA	NR	AA	WA	NR	AA	WA	AA	WA	L	WA	AA
Kayser <i>et al</i> (2006) ⁴⁵	AA	NA	WA	WA	NR	AA	WA	WA	L	L	WA	AA
Kleinlein (2010) ³⁶	NA	NA	L	NR	AA	WA	WA	WA	WA	L	AA	WA
Marsh <i>et al.</i> (2013) ⁴³	NA	NR	AA	WA	NR	AA	NA	WA	WA	L	WA	WA
Mazza <i>et al.</i> (2010) ⁴⁰	WA	NR	WA	NR	NR	AA	WA	AA	WA	L	WA	AA
Roberts & Penn (2009) ³⁷	NA	NA	WA	WA	NR	WA	AA	AA	WA	L	WA	WA
Rocha & Queirós (2013) ³⁹	NA	NA	NR	WA	NR	AA	WA	AA	WA	L	WA	WA
Roncione <i>et al.</i> (2004) ⁴⁷	AA	L	WA	NR	NR	AA	WA	WA	AA	L	AA	AA
Veltro <i>et al.</i> (2011) ⁴²	WA	WA	WA	NA	NR	WA	NR	AA	WA	L	L	L
Wang <i>et al.</i> (2013) ³⁸	AA	AA	WA	NR	AA	WA	WA	WA	AA	L	WA	WA
Wolwer & Frommann (2011) ⁴¹	AA	AA	WA	WA	NR	WA	WA	AA	WA	L	WA	AA

WA=Well addressed; AA=Adequately addressed, L=Limitations, NA=Not addressed; NR=Not reported

2.5.4 *Quality assessment ratings.*

Eight of the studies (62%) randomised participants to each of the treatment arms. Blinding was reported to have been at least adequately undertaken in just four (31%) of the studies. Attrition either did not occur or was not considered to have affected the outcomes in ten of the studies (77%), however seven (54%) of the studies either did not report or did not address the issue of variable attendance and its impact on the fidelity of the intervention provided. Only two (15%) of the studies reported that training to deliver the intervention had been provided to facilitators. In all studies the replicability of the intervention provided, based on the reporting and content of this, was at least adequate. All studies had adequate external validity, regarding the participants recruited to the study. The majority of studies (85%) had used a control group which either did not differ in relevant demographic, clinical and theory of mind outcome measure baseline scores, or had adequately controlled for such baseline differences in their analysis. All but one of the studies used an outcome measure that was considered to at least be an adequate measure of theory of mind when considering face validity, although psychometric properties had not been established for most measures. The analyses undertaken were at least adequate in the majority of studies (92%), but in all cases this was undermined, either due to having an inadequate sample size and thus inadequate power (92%) or a lack of clarity due to not reporting a power calculation (8%). Five (38%) of the studies were considered to meet the majority of the required areas for reporting, as assessed using TREND⁶⁹ or CONSORT⁷⁰ guidance as relevant. The utility of a further seven (54%) of the studies was not notably limited by omission of areas of relevance.

2.5.5 *Summary of findings with consideration of potential bias*

Eight (62%) of the studies reported significant improvements in the experimental group as compared to a control/comparison group on at least one of the Theory of Mind measures used^{38-41, 44, 46, 47, 63}. Two further studies^{43, 45} found within-group improvements but respectively did not identify any between-group differences and did not have a comparison group.

It is possible that significant improvements were not identified in the other studies due to inadequate power. In one study, one of the theory of mind measures were only introduced after some participants had completed the intervention, thus reducing the sample size available³⁵, whilst another experienced attrition of 30% from the intervention group³⁷. In another study³⁶ over a third of participants failed to complete the final post-intervention assessments, despite attrition from the intervention being a less severe 10%, resulting in insufficient power to adequately control for the possibility of type II errors.

In three of the studies where significant improvements were identified, these were not demonstrated across all of the theory of mind measures utilised^{43, 44, 46}. In another study it was not possible to tell if improvements were found across all outcomes measures used, due to incomplete reporting of results⁴².

None of the studies had at least adequately controlled for all areas of potential bias and so it must be noted that the outcomes could be affected to some degree by these.

2.6 Discussion

2.6.1 *Effect of social cognitive interventions on theory of mind ability*

The studies in this review showed that in many cases, a wide range of social cognitive interventions can lead to improvements in theory of mind abilities. In the majority of cases, the improvement of theory of mind was not the primary aim of the study, similar to studies in a previous meta-analysis of the effect of social cognitive interventions²³. It is encouraging to observe that many studies published since this meta-analysis was first available have continued to show that theory of mind ability is amenable to improvement^{38, 39, 41-44, 46}. In a number of studies where effect size was reported, this was found to be medium to large^{38, 39, 41, 44, 46}, suggesting this improvement is notable and can be potentially of a greater magnitude than initially indicated²³.

It is however recognised that none of the studies were rated as adequately addressing all of the quality criteria. In particular, the effectiveness of the interventions may have been artificially enhanced by a lack of adequate randomisation to treatment arm in 38% of the studies. This could potentially have resulted in participants who were considered to be more receptive to the intervention being allocated to the treatment group. However, almost two-thirds (64%) of the studies reporting an *improvement* following intervention were rated as having at least “adequately addressed” the need for randomisation. Common to many studies, it is recognised that individuals who met the inclusion criteria but had no interest in participating in the study’s intervention are likely to have declined to participate and therefore could not be allocated to any arm of the study. The level of effectiveness of these interventions should be viewed as being representative of that for those willing to undertake them, rather than for all individuals who would meet the inclusion criteria outlined for this review. It would

be helpful to also explore why some individuals may be resistant to engage in social cognition interventions, to remove barriers to engagement where possible.

2.6.2 Generalisability of study outcomes to everyday social situations

Although this review has highlighted the promising outcome that a variety of social cognitive interventions can lead to an improvement on measures of theory of mind ability, it is unclear whether this demonstrates that deficits in theory of mind are globally amenable to change. Many studies compared the intervention group's performance on outcome measures with that by an active and/or waiting list control group and established that the improvements shown were not due to practice effects. However, it is possible that while the intervention better prepared the individual to correctly complete the outcome measure(s), this task-specific improvement may not generalise to everyday life.

This question of the amenability of theory of mind deficits to change has been highlighted in studies involving people with a diagnosis of autism spectrum disorder (ASD). For example, a randomised controlled trial evaluating the effectiveness of a theory of mind training programme with children with ASD reported that although improvements in specific measures of theory of mind were found following this intervention, these were not reflected in evaluations of their everyday social skills⁷¹. A broader Cochrane review⁷² concluded that improvements from interventions based on a theory of mind model were not found to generalise to everyday situations, although this review also included improvements in other areas of social cognition rather than just specifically theory of mind abilities. It should however be considered that difficulties with generalisation are widely reported for individuals with ASD⁷³ and so this apparent lack of generalisation of improvements could be due to a factor specific to ASD, such as limited cognitive flexibility⁷⁴.

Studies that more broadly explore ability to generalise *knowledge* in schizophrenia suggest that this may vary dependent upon use of antipsychotic medication⁷⁵; how this may impact upon theory of mind skills specifically is unclear given the limited evidence base in this field. This therefore highlights the need for further research to be undertaken with people with schizophrenia, using consistent outcome measures across studies, including both traditional measures of theory of mind (such as false belief or “advanced” tests) along with measures with greater ecological validity. These could include *consistently* using assessments exploring the understanding of social interactions by showing recordings of these and asking questions to explore understanding, such as the TASIT⁵². In addition, ratings of an individual’s theory of mind abilities could be sought by those close to the individual; these ratings could be based on the areas explored in a questionnaire used regarding children with ASD⁷⁶.

2.6.3 *Durability of improvement*

The majority of studies included in this review assessed theory of mind ability post-intervention and did not report a follow-up assessment. The two studies that only undertook assessment six months after completion of the intervention^{38, 42} did find significant improvements on some measures of theory of mind, suggesting that such improvements can be durable. Due to the lack of a post-intervention assessment it was not possible to ascertain how participants’ post-intervention and follow-up abilities compared.

2.6.4 *Preference of interventions*

There was no single clearly preferable intervention when considering the areas of improvement or resource implications. The areas of improvement assessed included cognitive theory of mind abilities, ranging from first-order theory of mind false

belief stories to 'advanced' theory of mind scales, whilst other studies employed measures of affective theory of mind. It was noted that improvement in theory of mind ability following an intervention was not always consistent across all measures used; suggesting some interventions may only achieve a certain level of improvement and/or may be targeted at specific theory of mind abilities.

This wide range of assessments used, along with the variability in studies' adequate control of potential biases, meant that direct comparison across studies was more challenging. It was therefore not possible to conclude that one intervention was clearly more effective in terms of size of improvement achieved combined with consideration of resources required for its delivery.

2.6.5 Strengths and limitations of review

2.6.5.1 Inclusion criteria

Substantial consideration was given to the development of the inclusion criteria for this review. The inclusion of participants meeting diagnostic criteria for schizophrenia or schizoaffective disorder was applied in order to include as many studies as possible involving participants with schizophrenia, with or without mood disturbance. Studies including participants with diagnoses within the broader range of 'schizophrenia-spectrum' were not included due to the variability within these and given the recognition that many do not 'necessarily have a common etiology'⁵⁹. The search of a major database of unpublished dissertations and theses (ProQuest Dissertations and Theses) was included in an attempt to reduce the impact of potential publication bias⁷⁷ on the findings of the review.

The inclusion of non-randomised studies was undertaken to ensure that all interventions that may improve theory of mind abilities were captured, given that this is a relatively new area of research. This does however mean that studies with

the potential for bias in the recruitment of participants to treatment arms were included and so this must be acknowledged when considering the findings.

2.6.5.2 *Quality assessment criteria*

The development and use of bespoke quality criteria to assess areas pertinent to the aims of this review, rather than assessing the quality of the study overall, is considered a strength of this review. It is however acknowledged that these criteria were developed to distinguish between the quality of existing studies, in the context of a relatively new evidence base, as opposed to comparing studies to idealistic criteria. For example, 'blinding' was rated as 'well addressed' if it merely involved those administering the theory of mind measures being clearly blinded to participants' treatment allocation. However, it did not include participants being blinded to their treatment group along with both participants and assessors being blind to the study's hypotheses. Including such requirements in the highest level of rating criteria would have resulted in few or no studies receiving a high rating and most or all falling within one bracket, yet ranging in quality. This was therefore a practical approach for the review at this stage but it is noted that additional 'excellent' criteria would ideally be fulfilled were this field more advanced.

Review of the differences between independent raters highlighted that while the first rater (HL) had reviewed the quality of the methodology of the study, the second rater (GM) had included the quality of the reporting of the methodology when assigning ratings. Whilst the former approach captures the details of the studies included, the latter approach does highlight that clear reporting is necessary to enable busy clinicians to efficiently review and utilise the findings of studies developing new interventions. In many cases, although the studies covered areas recommended by reporting guidance (TREND⁶⁹ or CONSORT⁷⁰) and so were mostly rated as 'adequately addressed', the relevant information was not always organised as would be expected. For example, details of an intervention could be provided in the introduction³⁶, or information regarding attrition reported towards the end of

the discussion⁴⁵. In other cases, a clear statement regarding some areas of importance was not made at all. This meant that the paper had to be scrutinised to enable a judgement to be made, for example identifying whether attrition occurred by comparing the number of participants reported to have been recruited with the number presented in tables outlining the results⁴⁰. The use of clearer, structured reported, along with proof-reading of interpreted studies, would facilitate more efficient reviews of the evidence-base.

2.6.6 *Strengths and limitations of studies included in review*

All of the studies included in the review were rated as providing sufficient information regarding the interventions used to allow a good understanding of what the intervention entailed to be gained. This is clearly important when exploring the efficacy of relatively novel interventions. To enable further exploration into an intervention's suitability to be undertaken, given the interactive and dynamic nature of most interventions used, contact with authors or at least access to manuals referenced in the studies would however be required to ensure interventions were replicated reliably.

All of the included studies demonstrated failures to adequately address at least some of the key areas to control potential bias. It is unclear to what extent these may or may not have affected the findings of the studies. A clear need for future development in this area is for *a priori* power calculations to be undertaken and an adequate sample size utilised, with consideration given to the possibility of attrition. The attendance of participants to intervention groups should always be reported as this clearly impacts upon treatment fidelity.

The theory of mind measures used were on the whole considered to have reasonable face validity. However, their reliability and validity do not appear to have been formally assessed. This along with the differences in the areas of theory

of mind assessed makes it more challenging to compare the effectiveness of the various interventions used. Another issue to consider is that of ecological validity. The studies in this review did not include an assessment of whether participants' everyday theory of mind abilities had improved, for example as rated by professionals or others who knew them well. Such assessment would be more difficult to implement and it is likely that this approach was not utilised due to a lack of reliable, validated assessments incorporating a way of consistently rating an individual's everyday theory of mind abilities or difficulties. It is acknowledged that this is a relatively new area of study; consideration of this in future research in this field may enable the distinction between improvement on a task and more generalizable improvement. It is unclear if the improvements demonstrated in this review reflect a "training to task" effect, influenced by practice or learning more about what the test incorporated and exactly what to consider, or represent improvements that aid improved social cognition in everyday situations and interactions, which may be less predictable.

2.7 Conclusions

This systematic review demonstrates that a wide range of social cognitive interventions can be used to improve the theory of mind abilities of people with schizophrenia or schizoaffective disorder. It is currently unclear which interventions are preferable when considering the level of improvement achieved and the resource implications of each. While improvements in the measures used in the studies in this review appear likely to be beneficial in improving participants' social functioning^{6, 17, 8} it would be helpful in future studies to consistently utilise selected measures that assess increasing levels of theory of mind ability, including measures with greater ecological validity. This would enable exploration of the extent and particular aspects of theory of mind that improved following use of an intervention. It would also allow identification of the suitability of interventions for patients with differing severities of symptomatology (e.g. in-patients versus out-patients).

Crucially these studies require adequate power to detect all changes and the reporting of 'negative' findings would enable a greater understanding of the extent of the effectiveness of these interventions. Once one or more preferred interventions have been identified, their application in a high quality randomised controlled trial would enable exploration of their true effectiveness once bias has been fully controlled.

2.8 Declaration of interest and funding

The authors' employers are reported in the following section 2.9. There are no conflicts of interest. No specific funding was received to undertake this review.

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- HL designed the review and undertook all stages of the methodology, involving undertaking the systematic search, developing the quality review criteria and reviewing the quality of the studies. HL prepared the initial and final drafts of the article.
- GM independently reviewed the quality of a proportion of the studies included in the review.

- NF provided guidance during the design of the systematic review and critically revised a draft of the article.
- SO'R provided guidance during the design of the systematic review and reviewed amendments to the review.

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3 Empirical study

Presented in accordance with the guidelines for submission to the Journal of Clinical Psychology (Impact Factor 1.668). See Appendix D for author guidelines.

Social cognition deficits and violence in people with a diagnosis of schizophrenia

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Short title: Social cognition, violence & schizophrenia
Keywords: *Social cognition, facial affect recognition, theory of mind, violence, schizophrenia*

3.1 Abstract

Objectives

This study explored whether the extent of social cognition deficits displayed by people with schizophrenia differs between those with and without a substantial history of violence (SHV).

Method

22 males were recruited and allocated into a SHV or no-SHV group. Their facial affect recognition (FAR) and theory of mind (ToM) abilities were assessed, with measures used to control for potential confounding variables. Due to inadequate power, only a descriptive analysis is reported.

Results

The groups did not differ on overall FAR, but did vary on recognition of individual emotions. A trend of poorer sadness recognition and better faux pas detection in the SHV group was identified relative to the no-SHV group.

Conclusions

The findings of the study are limited by the small sample size, but patterns observed in the results highlight areas for further exploration. The strengths of this study's design and recruitment challenges are discussed.

3.2 Introduction

3.2.1 *Social cognition deficits, empathy and violence in schizophrenia*

It is widely reported that people with a diagnosis of schizophrenia have a range of cognitive deficits (Fioravanti et al., 2012; Heinrichs & Zakzanis, 1998). These include difficulties accurately recognising facial expressions of emotion (Kohler et al., 2010) and poorer performance in theory of mind tasks (Brune, 2005; Harrington et al., 2005; Sprong et al., 2007). It is possible that such social cognition deficits may be linked to violent offending. Models of empathy (Marshall et al., 1995; Marshall & Marshall, 2011) suggest that abilities in these areas are essential for empathy to be experienced. Low levels of empathy have been reported to have a “relatively strong” relationship with the use of violence by adults (Joliffe & Farrington, 2004) and to be linked to the use of violence in adolescents (Joliffe & Farrington, 2007). These outcomes were however confounded by a lack of control for intelligence and socio-economic status in some studies included in these reviews. The relation of empathy to the use of violence by people with schizophrenia has been highlighted as an area for further exploration (Bragado-Jimenez & Taylor, 2012).

It could be theorised that impairments in the social cognition abilities underlying the ability to experience empathy play a role in the use of violence. Following this theory, people with schizophrenia who have such social cognition deficits could be expected to be more likely to be violent. However, while people with a diagnosis of schizophrenia have been found to have a relatively greater likelihood of being convicted for a violent offence compared to the general population; however, only a minority of people diagnosed with schizophrenia commit violent offences (Wallace et al., 1998, 2004). Further understanding of the role of social cognition deficits and the use of violence by people with a diagnosis of schizophrenia is therefore required.

3.2.2 *Facial affect recognition and violence*

The first stage of the empathy models (Marshall et al., 1995; Marshall & Marshall, 2011) highlights that empathic accuracy cannot occur if one is unable to accurately identify how others feel. Deficits in this ability have been identified amongst violent offenders without schizophrenia, who have been found to have greater deficits in facial affect recognition than non-violent offenders or non-offenders (Gery et al., 2009; Hoaken et al., 2007; Seidel et al., 2013). These studies found that the violent offenders misinterpreted some expressions of emotion; for example neutral expressions were misinterpreted as showing disgust (Hoaken et al., 2007) and fearful expressions were thought to show surprise (Gery et al., 2009). Such deficits in facial affect recognition could therefore inhibit the experience of empathy and impede the development of a conditioned inhibition of violence (Blair, 1995). Such misinterpretations could also conceivably lead to reactive aggression and violent offending. Given the existing facial affect recognition deficits observed in people with schizophrenia (Kohler et al., 2010), exploration of any differences in the extent of these deficits in people with schizophrenia with a violent and non-violent history is clearly an important area to develop.

In contrast to the above, Silver et al. (2005) found that participants with schizophrenia or schizoaffective disorder with a history of severe violence (HSV) performed better than participants with schizophrenia or schizoaffective disorder without a history of severe violence (NSV) in the identification of happy, sad and neutral facial expressions. However, the ability of participants with schizophrenia with HSV to differentiate between the intensity of these facial expressions was impaired compared to those with NSV. These findings highlighted that further exploration involving assessment of the facial affect recognition of additional emotions was warranted to increase understanding of this area. The outcomes of other studies in this area are limited by use of a forensic group involving participants with charges for non-violent crimes (Wolfkühler et al., 2012) and

inadequate exploration of the potential violent history of comparison participants (Weiss et al., 2006; Wolfkühler et al., 2012).

Adequate assessment of participants' history of violence is therefore essential for future studies. A recently published study did report interviewing participants and reviewing case notes in order to assign participants to a violent or non-violent group (Demirbuga et al., 2013); no significant differences were found between these groups in their facial affect recognition abilities. For both groups there was a trend of poorest facial affect recognition for the individual emotions of sadness and fear.

3.2.3 *Theory of mind ability and violence*

It also appears possible that people are violent due to deficits in the second stage of the aforementioned empathy models (Marshall et al., 1995; Marshall & Marshall, 2011). These suggest that once another person's emotional state is accurately recognised, one needs to be able to view the other's perspective. This has clear links to theory of mind ability.

Majorek et al. (2009) found that people with schizophrenia recruited from a forensic service performed better on a measure of theory of mind ability than people with schizophrenia recruited from a general psychiatric setting. However, this study was also limited by a lack of assessment of the control group's history of offending and was not specific to violent offending only. One study to date has explored theory of mind ability in violent and non-violent groups of people with paranoid schizophrenia (Abu-Akel & Abushua-leh, 2004). Its findings suggested that those with a history of violence had relatively stronger cognitive theory of mind abilities, but were poorer at empathic inferencing than those without a history of violence. However, the findings were undermined by a lack of sufficient power due to an inadequate sample size. Additionally, the potential effects of psychopathy or

personality disorder were not controlled for, which could influence the reliability of the outcomes of this study.

3.2.4 Hypotheses

3.2.4.1 Principal hypotheses:

Facial affect recognition (overall) -

- i) There will be a significant difference between the facial affect recognition ability of the SHV and LNHV groups (*as measured by the proportion of participants whose overall facial affect recognition score on the PoFA is classed as “normal”*).

Recognition of individual emotions -

- ii) There will be significant differences between the SHV and LNHV groups in their emotion-specific facial affect recognition ability (*as measured by the proportion of participants in each group who are classed as “normal” in their recognition of a specific emotion in the PoFA, for each of the six emotions included*).

3.2.4.2 Secondary hypotheses:

- iii) There will be a significant difference between the SHV and LNHV groups in their first-order false belief detection ability (*as measured by the proportion of participants in each group who provide the correct response to the Unexpected Transfer Test*).
- iv) There will be a significant difference between the SHV and LNHV groups in their second-order false belief detection ability (*as measured by the proportion of participants in each group who provide the correct response to the Location Change Task*).

- v) There will be a significant difference between the SHV and LNHV groups in their faux pas detection ability (*as measured by the proportion of participants in each group whose overall faux pas detection score on the Faux Pas Recognition Test is classed as “normal”*).

3.3 Methods

3.3.1 Participants

To be included in the study, all participants had have capacity to provide consent to participate, as judged by their care team. Inclusion criteria included having a diagnosis of schizophrenia or schizoaffective disorder and being aged 18-66. As one of the services recruited from only accepted male patients, only men were included in the study to control for the potential impact of gender differences on facial affect recognition (Kohler et al., 2000; Weiss et al., 2007), faux pas recognition (Söderstrand & Almkvist, 2012) and self-reported empathy (Davis, 1980).

3.3.2 Exclusion criteria

Clients were not eligible for inclusion if they had a diagnosis of Autism Spectrum Disorder (ASD), as it is well established that people with ASD have deficits in facial affect recognition (Bormann-Kischkel et al., 1995; Law Smith et al., 2010). Theory of mind deficits have been reported for even adults with high functioning ASD (Baron-Cohen et al., 2001; Beaumont & Newcombe, 2006). Additionally, studies involving people who had diagnoses of Asperger’s syndrome found they scored lower on measures of cognitive empathy compared to controls (e.g. Dziobek et al., 2008; Rogers et al., 2007). Therefore, clients with a diagnosis of ASD were not invited to participate, as this would have been a conflicting variable.

Another exclusion criterion used was a diagnosis of psychopathy, as people with psychopathy are known to be impaired in their recognition of fearful expressions (Blair et al., 2004; Iria & Barbosa, 2009). While some studies have not found differences in theory of mind ability between people with and without psychopathy (Blair et al., 1996; Ritchell et al., 2003), others have reported deficits in faux pas detection (Dolan and Fullam, 2004) and affective theory of mind tasks (Shamay-Tsoory et al., 2010). It was judged that including participants with a diagnosis of psychopathy would undermine the reliability of the study's results. However, screening for psychopathy was not undertaken, as the prevalence of people with psychopathy in Scotland is low. Coid et al. (2009) reported a prevalence of 0.6% in the 'household' population of England, Scotland and Wales, whilst Cooke (1995) found 3% of adult male prisoners in Scotland met the criteria for psychopathy. To screen for psychopathy would have extended the length of the study and would raise ethical issues, given the resulting implications of potential preventative detention for a participant scoring highly on an assessment of psychopathy (Buchanan & Leese, 2001; Feeney, 2003).

Another exclusion criterion was having had a traumatic brain injury (TBI) where this included a loss of consciousness, hospital inpatient treatment *and* was considered to have an ongoing impact on functioning. Deficits in facial affect recognition along with theory of mind, including abilities to correctly answer tests of first and second order false belief and detect faux pas, have been identified in people with severe TBIs when compared to controls (Bibby & McDonald, 2005; Milders et al., 2003). For practicality, clients with less severe head injuries were included where no change in their functioning was reported.

In order to control for between-group differences, clients with a learning disability were not recruited, due to difficulties finding matched participants for the no-SHV group. Such balancing was necessary given that people with learning disabilities

have deficits in facial affect recognition and theory of mind abilities (Ashcroft et al., 1998; Owen et al., 2001; Söderstrand & Almkvist, 2012).

Lastly, participants without a reasonable understanding of the English language were not invited to participate. Due to copyright, translation of the measures was likely to be problematic and in many cases the existing normative data for these have been developed by use of the measures in their existing form with English speakers.

3.3.3 Recruitment

Participants were recruited from a high security forensic mental health hospital (HSFMH) and two community mental health teams (CMHTs) from three NHS health boards in Scotland. Staff within these services approached clients under their care who met the inclusion criteria of the study, to provide information regarding the study and seek consent for the researcher to contact them. Where this consent was provided, the researcher contacted the client to provide further information about the study and asked if they wished to participate. Testing was held over one to three sessions, depending on participants' wishes and fatigue. Where testing was split, all assessments relating to a recent time frame were completed within the first two sessions, which were held no more than two weeks apart.

3.3.4 Design

This study employed a cross-sectional design. Participants were classified into one of two groups by review of case notes and use of a questionnaire exploring their history of violence. Ratings were assigned based on their history of violence by use of a modified version of the "Rating from previous record" subscale of the Violence Rating Scale (Robertson et al., 1987). Participants were classed as having a "lower/no

history of violence” (LNHV) if they received a rating of 0 or 1; all others were classed as having a “substantial history of violence” (SHV). Please refer to Appendix E for details of this scale.

3.3.5 Measures

3.3.5.1 Control measures

Four measures were used to identify whether the groups differed on variables that could each independently affect performance on the experimental measures. These were included so that if differences were identified, these could then be controlled for in the statistical analysis.

a) International Personality Disorder Examination Screening Questionnaire (IPDE-SQ) (DSM-IV) (Loranger, 1999)

Deficits in facial affect recognition have been found for people with some (Marissen et al., 2012), but not all types of personality disorders (Mitchell et al., 2014).

Additionally, people with a diagnosis of personality disorder (but not schizophrenia) have been found to perform better on second order theory of mind tests than people who have a diagnosis of schizophrenia but not personality disorder (Murphy, 1998, 2006). Given this, it was considered important to control for the presence of personality disorder. Studies within Dutch forensic systems or British prisons have found that a high prevalence of people who have committed offences have personality disorders (Ruiter & Trestman, 2007; Slade & Forrester, 2013). It was also known that many patients at the HSFMH had diagnoses of personality disorder (current records show that over a third of patients with a diagnosis of schizophrenia or schizoaffective disorder also have one or more diagnoses of personality disorder), so to exclude patients with a personality disorder would have excluded a large number of potential participants and would not have reflected the clinical reality of this population. This screening questionnaire was therefore used to identify and compare the prevalence of

participants where further clinical assessment would be advisable to ascertain whether they met criteria for diagnosis of a personality disorder. The IDPE-SQ is not diagnostic but identifies whether further clinical assessment is warranted. It is acknowledged that its specificity is limited in preference of high sensitivity, in order to avoid false negative outcomes (Álvano-Brun & Vegue-González, 2008; Magallón-Neri et al., 2013). This tool was used due to its widespread clinical use and to aid the detection of the potential for participants to have one or more personality disorders.

b) Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1999)

The PHQ-9 is a brief self-report questionnaire assessing the presence and severity of symptoms of depression within participants for two weeks prior to the time of testing. Assessment of depression within participants was necessary as people with depression have been found to show poorer facial affect recognition (Anderson et al., 2011; Feinberg et al., 1986; Surguladze et al., 2004) along with deficits in cognitive theory of mind abilities (Cusi et al., 2013; Wolkenstein et al., 2011).

The established score for clinically significant levels of depression has been shown to have a sensitivity of 88% and a specificity of 88%, with excellent internal reliability (Kroenke et al., 2001). Its outcomes have been found to have a high correlation with independent, blind ratings made by experienced mental health professionals using an overview of the established Structured Clinical Interview for DSM-III-R (Spitzer et al., 1992) along with diagnostic questions from the Primary Care Evaluation of Mental Disorder (PRIME-MD) (Spitzer et al., 1994). The strong psychometric properties of this measure, along with its focus on assessment of current symptomatology and its brevity meant it was particularly suitable for this study.

c) Autism Spectrum Quotient (AQ-10) (Allison et al., 2012)

As previously outlined, control for the confounding variable of ASD is necessary. While those with a diagnosis of ASD were excluded from the study, consultation

with clinicians in one of the CMHTs identified the need to screen for the possibility of ASD in case this had not been diagnosed. Whilst this ten-item questionnaire in no way replaces a full assessment for ASD, it enables differentiation between those who are unlikely to meet diagnostic criteria for ASD and those where it is possible that they have undiagnosed ASD. Its use with a large sample size has identified a suitable cut-off score providing good sensitivity and specificity (Allison et al., 2012) and its brevity meant it was suitable for inclusion in this study.

d) Psychosis Evaluation Tool for common Clinical Caregivers (PECC) (Lindström et al., 1997)

The positive, negative and anxiety subsections of the PECC were used to assess participants' symptomatology of schizophrenia. This tool was selected as it has been reported to have a 'more robust factor structure' in comparison to the 'Positive and Negative Syndrome Scale' (PANNS) (Lindström et al., 2012) and is briefer to complete, so was more suitable for the purposes of this study. It has been established that 'both the inter-rater and interscale validity of the PECC are satisfactory' (Hert et al., 2002). The tool was of particular use as an abbreviated version of the PECC is routinely completed with all patients in the HSFMH and this enabled comparison with ratings assigned by the participants' care team. For all participants, a review of their care team's observations of their presentation, as recorded in their care notes, was also undertaken. This corroborative information was considered when assigning ratings, along with participants' responses to the semi-structured interview and their presentation during the testing process.

The symptomatology experienced by participants was assessed in order to control for differences between groups in the prevalence of their negative and positive symptoms. In some studies, negative symptoms of schizophrenia have been associated with deficits in facial affect recognition (Borod et al., 1993; Tseng et al, 2013), whereas in another an association was found between poor facial affect recognition and positive symptoms of schizophrenia (Chambon et al., 2006). Deficits

in theory of mind abilities have also been linked to negative symptomatology in schizophrenia (Lincoln et al., 2011; Rabin et al., 2014). Anxiety has also been linked with impaired facial affect recognition (Kessler et al., 2007; Palm et al., 2011) and theory of mind (Hezel & McNally, 2014). It therefore it was important to identify if there were differences between groups in the prevalence of participants experiencing these symptoms and to control for these if differences were found.

3.3.5.2 *Experimental measures*

a) Pictures of Facial Affect (PoFA) - Facial Expressions of Emotion: Stimuli and Tests (FEEST) (Young et al., 2002)

The Pictures of Facial Affect (Ekman & Friesman, 1976) were presented on a computer in accordance with the presentation instructions used in the FEEST (Young et al., 2002). This involved preceding testing by asking participants for examples of times they had experienced each of the emotions, to ensure they understood the meaning of each. Each picture was displayed for 5 seconds with the names of each possible response shown on screen throughout; response time was unlimited. The use of this test enabled assessment of participants' facial affect recognition ability for happiness, sadness, anger, disgust, fear and surprise. Their validity is well established by their widespread use in many research studies, including recent studies in the field of social cognition deficits (e.g. Spikman et al., 2012; Woodbury-Smith et al., 2005; Wright et al., 2008). Satisfactory internal consistency reliability has been demonstrated (Young et al., 2002) with the normative data available being comparable to that arising from the use of original Ekman and Friesman (1976) data.

b) Unexpected Transfer Test (Wimmer & Perner, 1983).

This is a brief first-order theory of mind task that assesses an individual's ability to recognise that others may hold false beliefs and to attribute these correctly.

c) Location Change (Ice Cream Van) Task (Perner & Wimmer, 1985)

This second-order theory of mind task assesses an individual's ability to correctly infer beliefs held by another about a third party's beliefs.

Both of these tests were explained verbally, with pictures used as visual aids for increased comprehension. Participants were advised that the story could be read more than once if desired.

False belief tasks have been found to generally show good reliability (Grant et al., 2001; Hughes et al., 2000). These particular tests were chosen due to their wide ranging use in existing research that has used first-order (e.g. Baron-Cohen et al., 1985; Doody et al., 1998; Reed, 1994; Yirmiya et al., 1996) and second-order theory of mind tests (e.g. Baron-Cohen, 1989; Doody et al., 1998).

d) Faux Pas Recognition Test (Adult Version) (Stone et al., 1998)

This is an advanced theory of mind test, which assesses an individual's ability to correctly identify whether a faux pas has been made and explain what it was. The passages were read to participants as many times as required and were also presented in written format to reduce demand on participants' working memory. This test was chosen as it includes a comprehension test to differentiate between poor performance resulting primarily from incomprehension or due to advanced theory of mind deficits. It has been shown to be more challenging than second-order theory of mind tests (Baron-Cohen et al., 1999) and has been used in a similar study to this (Abu-Akel & Abushua'leh, 2004). It has been demonstrated to have excellent internal consistency and inter-rater reliability and to have significant correlations with other measures of theory of mind (Söderstrand & Almkvist, 2012).

e) Interpersonal Reactivity Index (IRI) (Davis, 1980)

This is a self-report measure of empathy that fits with facets of Marshall (2002)'s revised model of empathy and is regularly used in research relating to empathy (e.g.

Proctor & Beail, 2007). To ensure participants' understanding of the questions, a copy was provided to participants to read, with the questions read to them with emphasis places on potential areas of misinterpretation (e.g. "Sometimes I *don't* feel very sorry for other people").

The IRI subscales have been reported to have 'substantial' internal and test-retest reliability (Davis, 1980), whilst a longitudinal study reported stability of IRI outcomes in people with schizophrenia (Haker et al., 2012). Concurrent validity with other measures of empathy has been reported, with moderate associations found between its subscales and those of the 'Empathy Quotient' (Lawrence et al., 2004).

Further information regarding the scoring and interpretation of each of the measures used can be found in Appendix E.

3.3.6 *A-priori power calculations*

3.3.6.1 *Planned analysis to address primary hypothesis*

A *chi-squared* test of contingencies was planned to be undertaken to identify whether there were differences between the number of participants (for matched size groups) in the SHV and LNHV groups who were classified as "normal" for overall facial affect recognition ability. Further information regarding this classification can be found in Appendix E. It was noted that the analysis would need to first be checked to ensure that the minimum expected frequency for each possible outcome was achieved (Clark-Carter, 2004). If this was not the case, it was planned that Fisher's exact probability test would be used.

In order to undertake an a-priori power calculation, relevant studies were reviewed to guide selection of an anticipated effect size. At the time this occurred (early 2012), there was a lack of accessible studies comparing people with schizophrenia with and without a history of violence. Therefore, studies comparing facial affect

recognition ability in sexual offending and non-sexual/non-violent offending groups, but without a diagnosis of schizophrenia, were instead reviewed. These reported differences between groups that had or were approaching large effect sizes (Gery et al., 2009; Hoaken et al., 2007). Extrapolating from these findings, it was considered possible that similar differences could be found for violent and nonviolent groups of people *with* a diagnosis of schizophrenia. This size of effect was therefore utilised when calculating the minimum sample size required to provide sufficient power to detect a difference between groups in this study. Incorporating this into a power calculation using G*Power (Erdfelder *et al.*, 1996), the required sample size to achieve power of 0.8, with $\alpha=0.05$ and $df=1$ was calculated to be 32 where a large effect size existed.

In addition to comparing the number of participants in each group classed as “normal” for their overall facial affect recognition, the number of participants classed as “normal” for the recognition of the six individual emotions assessed would also be compared between groups. It was recognised that undertaking multiple comparisons would increase the risk of a type I error occurring. A correction would therefore be made to the level at which a difference would be considered to be statistically significant. Since the Bonferroni correction can be excessively conservative when used for a number of tests, diminishing the power to detect a true effect (Bland, 2000), it was identified that use Holm’s sequential adjustment (Holm, 1979) would be more suitable.

3.3.6.2 *Planned analysis to address secondary hypotheses:*

As performance on the measures used to address the secondary hypotheses was to also be classified as “normal” or “impaired”, it was again planned to undertake a *chi-squared* test of contingencies to identify whether there were differences between the SHV and LNHV groups’ performance on false belief and faux pas tasks. As previously outlined, if the minimum expected frequency for each possible outcome was not achieved, Fisher’s exact probability test would be used instead.

It was not possible to determine what the likely effect size of any differences in the two groups' performance on these measures (if any) would be, as existing studies in the field were inadequately powered and did not report sufficient detail to allow effect sizes to be calculated (Abu-Akel & Abushua'leh, 2004; Majorek et al., 2009). Therefore, it was decided that the **same** minimum sample size as identified for addressing the primary hypotheses would be used. This would enable a difference to be identified if a large effect size was present. It was acknowledged that this would mean a medium effect size could be present but not be detected, but it was considered that this would be more feasible to recruit. However, if it were possible to recruit more participants then recruitment would be continued; use of G*Power (Erdfelder *et al.*, 1996) with the same parameters as previously outlined identified that a sample size of 88 would be required for a medium effect size to be detected for this analysis.

3.3.7 *Ethical approvals*

The study was reviewed by the South East Scotland Research Ethics Committee with ethical approval granted. For each recruitment site, approval was obtained from the Research and Development departments of the NHS Health Boards before any participants were recruited. All participants provided consent to be contacted by the researcher and consent to participate in the study.

3.4 **Results**

3.4.1 *Recruitment*

A total of 24 participants were initially recruited to the study. Testing was discontinued with one participant who disclosed suicidal intent; his scores were not

included in the analysis as not all control measures had been completed. Another participant's scores are not currently included due to a significant discrepancy in his reported and alleged history of violence. The majority of the participants included in the analysis (73%) were recruited from the HSFMH, with the remainder recruited from CMHTs.

3.4.2 *History of violence ratings*

The ratings of participants' histories of violence are shown in Table 3.1. Five participants (23%) received a rating of 0 or 1 and were classed as having a "lower/no history of violence" (LNHV); all others were classed as having a "substantial history of violence" (SHV) (n=17).

Table 3.1. Ratings of participants' history of violence.

Rating	Number of participants (n=22)	% of total
4	12	54.5
3	5	22.7
2	0	0
1	4	18.2
0	1	4.5

3.4.3 *Power*

The total sample size (n=22) does not meet the minimum required sample size of 32 (if a large effect size were present) as calculated by a-priori power analysis for the primary analysis. The power that would be achieved if the planned analyses were run is further reduced due to the sample sizes being uneven (Clark-Carter, 2010, p618). This means that if differences between the SHV and LNHV groups exist, or there is a relationship between performance on social cognition measures and self-reported empathy, they may well not be detected due to the increased probability of a type II error. The likelihood that a type I error will be made is also increased

(Christley, 2010), so any significant findings obtained from running the statistical analysis would also be undermined. For this reason, the hypotheses of the study are not addressed in this article through statistical analysis, as the outcomes would be unreliable. Instead, only descriptive statistics are presented in this article with trends and areas of interest highlighted. These should be interpreted with caution, as in most cases they were not found to be statistically significant (details of this are reported in the supplementary results chapter) and even those which were significant arose from an underpowered study.

3.4.4 *Demographics*

Participants' ages ranged from 21 to 66 with an overall average age of 39 years (SD=12.8). All participants were prescribed one or more forms of psychiatric medication. Two participants (40%) in the LNHV group reported drinking alcohol within the last 48 hours but not on the day of testing; this was reported to be within recommended limits. None of the participants who could have access to substances (i.e. those recruited from CMHTs) reported using other drugs aside from prescribed medication in the last 48 hours. Demographic information comparing each of the two groups (SHV and LNHV) are presented in Table 3.2.

Table 3.2. Demographic information of participants by history of violence group.

Demographics	SHV group (<i>n</i>=17) (where given, % of group)	LNHV group (<i>n</i>= 5) (where given, % of group)
<i>Age</i>		
Mean age at testing	37 (<i>SD</i> =13.7)	45.6 (<i>SD</i> =8.6)
Age range	21-66	35-54
<i>Diagnosis</i>		
Schizophrenia (including subtypes)	16 (94.1%)	5 (100%)
Schizoaffective disorder	1 (5.9%)	0 (0%)

3.4.5 Control measures

The outcomes of each of the control measures used, by history of violence group, are shown in Table 3.3. It was noted that the majority of participants in each group were classed as potentially meeting criteria for diagnosis of a personality disorder, while the prevalence of participants whose responses on the AQ-10 suggested a need for further ASD assessment was low across both groups. Less than half of participants in each group reported experiencing a clinically significant level of depression in the two weeks prior to testing. Almost a third of the SHV group did not display positive or negative symptoms of schizophrenia, suggesting that these symptoms were well controlled by their medication.

Table 3.3. Outcomes of control measures for each group.

Control measure	Frequency (where given, % of group)	
	SHV group (<i>n</i> =17)	LNHV group (<i>n</i> = 5)
<i>IPDE screen</i>		
Personality disorder(s) potentially present	15 (88.2%)	5 (100%)
<i>AQ score</i>		
Score supports further assessment for ASD	1 (5.9%)	1 (20%)
<i>PHQ9 – using score of 10 as clinical cut-off</i>		
Depressed	4 (23.5%)	2 (40%)
<i>PECC score</i>		
No. ptps with positive symptoms present	8 (47.1%)	4 (80%)
Mean positive symptoms score (max. 21)	6	9.8
No. ptps with negative symptoms present	10 (58.8%)	5 (100%)
Mean negative symptoms score (max. 28)	8.5	10.4
No. ptps with positive and/or negative symptoms present	12 (70.6%)	5 (100%)
No. ptps with anxiety present	11 (64.7%)	4 (80%)
Mean anxiety score (max. 7)	3.1	3.4

3.4.6 Experimental measures

Descriptive statistics of outcomes on the experimental measures used are shown in Table 3.4. The imbalance of group sizes must be highlighted when considering these outcomes; were each group to be of an equal size, sufficiently large to be adequately powered, the outcomes could potentially be quite different.

Less than half of participants in each group scored within the “normal” range for their overall facial affect recognition ability. The emotion for which the highest number of participants in the SHV were impaired in detecting was sadness, whereas for the LNHV group it was fear. The majority of participants in both groups were able to correctly answer the first order theory of mind false belief test. Performance on the second order theory of mind false belief test was relatively poorer,

particularly for the SHV group. The LNHV group displayed particular difficulty with faux pas detection, whereas the rate of 'normal' faux pas detection in the SHV group did not notably differ from the proportion of those correctly answering the second order theory of mind test.

Consideration of participants' performances on the theory of mind tests on a case by case basis showed that of those who answered the second-order false belief task correctly, all had correctly answered the first-order false belief task. However, 50% of all participants who did perform within the normal range for the faux pas test *did not* answer the second-order theory of mind test correctly.

Table 3.4. Outcomes of experimental measures for each group.

Social cognition measure	SHV group (n=17) (where given, % of group)	LNHV group (n= 5) (where given, % of group)
<i>Overall classification of facial affect recognition score, by age</i>		
Normal	7 (41.2%)	2 (40%)
<i>No. ptps scoring within normal range for each emotion</i>		
Happiness	11 (64.7%)	4 (80%)
Sadness	7 (41.2%)	5 (100%)
Anger	11 (64.7%)	3 (60%)
Disgust	12 (70.6%)	4 (80%)
Fear	11 (64.7%)	2 (40%)
Surprise	16 (94.1%)	4 (80%)
<i>Theory of Mind (ToM) 1st-order false belief story</i>		
Correct	16 (94.1%)	5 (100%)
<i>ToM 2nd-order false belief story</i>		
Correct where control questions correct	10 (58.8%)	4 (80%)
<i>Faux pas detection - classification based on detection score for all stories completed</i>		
No. ptps within normal range	11 (64.7%)	1 (20%)
No. ptps who answered control questions incorrectly on one or more stories	6 (35.3%)	2 (40%)
<i>Comparison of scores across ToM measures</i>		
No. ptps answering 2 nd order test correctly, who <i>did</i> answer 1 st order test correctly	10 (58.8%)	4 (80%)
No. ptps answering 2 nd order test correctly, who <i>did not</i> answer 1 st order test correctly	0 (0%)	0 (0%)
No. ptps whose FP detection score fell in normal range, who answered 2 nd order test correctly	6 (35.3%)	1 (20%)
No. ptps whose FP detection score fell in normal range, who <i>did not</i> answer 2 nd order test correctly	5 (29.4%)	1 (20%)

3.5 Discussion

3.5.1 *Summary and reflection on findings*

3.5.1.1 *Facial affect recognition*

A large proportion of participants displayed deficits in their facial affect recognition ability; this is consistent with the wide body of research that has established that people with schizophrenia have significant deficits in their facial affect recognition ability when compared to healthy controls (Kohler, 2010; Savla, 2013). While the proportion of participants scoring within the “normal” range for overall facial affect recognition ability did not differ between the SHV and LNHV groups, differences were observed in the recognition of individual emotions by each group. Participants in the SHV group displayed a particular deficit in their ability to accurately recognise sadness, whereas all participants in the LNHV scored within the normal range for recognition of this emotion. The LNHV group showed a trend towards a similar deficit in their identification of fear. Edwards et al. (2002) noted that difficulties in the recognition of these emotions in particular have been reported in a number of studies exploring facial affect recognition in people with schizophrenia, although this is not consistent across all studies (e.g. Kohler et al., 2003; Tsoi et al., 2008). It is unclear what may contribute to, or result from these emotion recognition deficits differing between groups. However, these outcomes are likely to be influenced by the notable difference in the sample size of each group and overall inadequate power for reliable comparison of the two groups. Further exploration with larger sample sizes would be required to confirm the presence of these observed trends.

The use of the PoFA to assess facial affect recognition meant this task was potentially more challenging than in everyday situations, where expressions are not static and are supplemented with cues such as speech content, body language and other people’s reactions. However, performance on this task could be placed in

context due to its inclusion of normative data, enabling identification of deficits in participants' facial affect recognition ability compared to "normal" controls. The misinterpretations demonstrated by participants could contribute to their use of violence in everyday situations, if they misinterpreted another person's expression to be negative (for example, to show anger or disgust) where this was not warranted by the situation.

3.5.1.2 *Theory of Mind ability*

While the groups did not notably differ in their ability to correctly answer first order false belief tasks, as also observed by Abu-Akel and Abushua'leh (2004), a trend was observed for the SHV group to experience greater difficulty than the LNHV group with the second order false belief task. However, this did not extend to performance on the faux pas task, where the majority of the LNHV group displayed substantial difficulty compared to just over a third of participants in the SHV group.

Performance by each group on these two measures therefore follows the opposite pattern to that reported by the one other study which is known to have explored this area (Abu-Akel & Abushua'leh, 2004). The reliability of the findings of either study are however limited by their small sample sizes; in the case of this study the imbalance of sample size between groups adds a greater need for cautious interpretation of these results.

Nevertheless, the observation in both studies that performance of participants appears to vary across the three theory of mind measures is particularly interesting. These measures were selected as they are traditionally considered to be of increasing difficulty; development of the ability to solve second order false belief tests has been found to develop at a later age than that for first order false belief tasks (Muris et al., 1999; Perner & Wimmer, 1985). The development of the ability to detect faux pas has been reported to develop later still and is therefore considered to be more challenging (Baron-Cohen et al., 1999). However, in this study, deficits by each group on their second-order theory of mind ability did not appear to translate

into relatively proportional deficits in the supposedly more challenging faux pas detection test. Indeed, when considered on an individual basis, half of participants in this study whose faux pas detection score fell within the normal range *did not* answer the theory of mind and/or control questions correctly for the second-order false belief task.

This lack of positive inter-correlation between measures has also been observed in a study involving participants with dementia, where those with Alzheimer's disease (AD) also had greater difficulty with second-order theory of mind test than the faux pas tests (Gregory et al., 2002). It was suggested that participants with AD may have experienced greater difficulties on the faux pas test due to demands on episodic and working memory. In an attempt to reduce such demands, participants in this study were reminded that they could ask for the story to be read more than once and the story was also provided in writing, to help participants to more easily follow and process the story. It was however observed that some participants declined the option of having the story read again, but then went on to provide an incorrect answer.

Similarly, the second-order false belief task (the 'Location Change Task') also posed demands on an individual's attention and verbal memory. Despite the use of illustration to visually supplement the verbal story, it was possible that participants who did not ask for the story to be repeated (as offered prior to it being read) may have answered incorrectly due to difficulty attending to or remembering all of the story.

Future studies could therefore include two readings of all stories as default to try to eliminate the potential effect of the high demand on working and episodic memory on assessed theory of mind ability, given the established deficits in verbal working memory identified in people with schizophrenia (Zilles et al., 2010). It is also possible that variability in the medication taken by participants may have impacted

on their performance in these tasks. The lack of consistent outcomes of studies exploring the impact of antipsychotic medication on theory of mind ability (e.g. Kucharska-Pietura et al., 2012; Savina & Beninger, 2007) and working memory (e.g. Meltzer & McGurk, 1999; Green et al., 1997) makes it challenging to anticipate the direction of such an effect.

Despite these limitations, these measures are useful as they allow assessment of an individual's ability to understand others' perspectives, in the moment. In particular, the Faux Pas test has strong face validity with the conceptual link of poor theory of mind and use of violence. It is specifically designed to measure an aspect of theory of mind that clearly contributes to social functioning and could be a potential trigger for violence. If an individual is not aware that they have committed a faux pas, they may continue to make these and cause offence to others, whilst also not taking steps to rectify them as may otherwise be the case. This could lead to others reacting with verbal or physical aggression, leading to the individual responding with physical violence.

3.5.2 Strengths and limitations of study

3.5.2.1 Sample size

The clear limitation of this study is the inadequate sample size recruited, which has meant that the original hypotheses of the study cannot be reliably addressed and the trends observed must be interpreted with caution. This was due to significant challenges with recruitment for the LNHV group. During the design of the study, staff members of various professional backgrounds in the CMHTs of one NHS health board were consulted regarding the feasibility of the study design. All who were contacted provided their opinion that recruitment of the minimum sample size would not be problematic, as a large number of their patients met the study's inclusion criteria. Unfortunately, despite various forms of ongoing contact with staff members in these teams, no participants at all were actually recruited by that health board. This was potentially partly due to a larger, longitudinal study involving the

same client group being undertaken at the same time, which offered financial incentives for participation. Approvals to recruit from CMHTs in two additional health boards were therefore sought and obtained, with the study again publicised through presentation at team meetings and contact by email and telephone. This resulted in six participants being recruited, five of whom met criteria for inclusion in the LNHV group.

By contrast, the majority of participants in the SHV group were recruited from a HSFMH where there was a large number of patients meeting the study's inclusion criteria and crucially, where members of the research team were based. This greatly facilitated the recruitment and testing process for this group.

The low recruitment rate to the LNHV group, despite continued efforts at recruitment for over a year, demonstrates the difficulty of recruiting within this population and raises the issue of the use of financial incentives to increase recruitment rates. Participation in this study took a substantial amount of time and effort for participants, so to reward this through at least minimum wage payment could be viewed as fair reimbursement. Concerns have however been raised regarding payment potentially providing "undue inducement" (Macklin, 1981). When the effect of financial incentives on willingness to participate in research was explored with people with schizophrenia, it appeared that high payments could increase the likelihood of taking part in studies where there was more than minimal risk, but that a majority would not participate in high-risk studies regardless of payment. Additionally, the potential of personal benefit from participating was identified to be of importance when deciding whether to participate. Further exploration was recommended to understand these relationships more clearly (Dunn et al., 2009).

Given the difficulties involved with recruitment to this study and the observation that other studies in this field have also been limited by a small sample size (e.g.

Abu-Akel & Abushua-leh, 2004; Wolfkühler et al., 2012), future studies in this area should therefore give thorough consideration of these real recruitment challenges. Whilst keeping in mind the importance of not providing undue inducement, it appears practical for future studies to propose the use of reasonable incentives for participation to then be considered and reviewed by ethical committees. It seems that working within a team with direct clinical care of clients meeting the study's criteria would also aid the recruitment process, both due to team members perhaps being more motivated to recruit to a colleague's study and through increased opportunities to raise potential participants' awareness of what the study involved (Kaminsky et al., 2003; Woodall et al., 2010). For this study, it appears unlikely that continuing with recruitment without these factors being in place would result in sufficient numbers of participants being recruited within a reasonable timeframe[^].

3.5.2.2 Formal assessment of cognitive functioning

An area for consideration would be the potential inclusion in future studies of a formal assessment of intellectual functioning. A decision was taken not to include this in this study, as in practice an assessment of a client's intellectual ability would usually be undertaken where their clinical team queried the possibility of them having a learning disability. It was therefore judged that to include an assessment of cognitive functioning would excessively lengthen the duration of testing for each participant. Potential participants with a diagnosis of a learning disability were not referred in by the CMHTs and so, to ensure a matched sample in this area, potential participants in the HSFMH with a learning disability were not recruited.

[^] The lead researcher would however intend to continue to recruit to the study in future if employed within a team working with clients meeting criteria for inclusion in the LNHV group.

The lack of formal cognitive assessment did however mean that the proportion of participants in each group with, for example, an average versus a borderline level of intellectual functioning were not controlled for. This could be of relevance given that IQ may play a role in the ability of individuals with schizophrenia to complete theory of mind tasks (Brüne, 2003; Pickup & Frith, 2001). The possible future inclusion of such an assessment would therefore need to be considered in light of the aforementioned recruitment challenges.

3.5.2.3 Rating of history of violence

A particular strength of this study was that thorough consideration of a participant's full history of violence was undertaken and rated through use of the modified "Rating from previous record" subscale of the Violence Rating Scale (Robertson et al., 1987) (see Appendix E). This enabled all acts of violence towards others in a participants' life to be considered when rating their history of violence, rather than this being limited to those for which a participant had received a criminal charge. The latter approach means that participants who have committed assaults for which they have not been charged are not included and severely limits the validity of findings. Additionally, the use of this tool and the development of an accompanying questionnaire and review of case notes allows a participants' use of violence to be rated, rather than coding participants by whether or not they have a forensic history, which could involve various non-violent crimes. This was therefore a vital improvement upon the design of most other studies in this field, which were affected by the major limitation of a lack of differentiation between forensic and violent samples and inadequate assessment of the comparison group's history of violence (Majorek et al., 2009, Weiss et al., 2006; Wolfkühler et al., 2012).

3.5.2.4 Lack of contemporaneous assessment of social cognition abilities and use of violence.

A key limitation of this study is that the measures of participants' social cognition abilities and symptomatology of schizophrenia were not assessed at the time they committed acts of violence. It is therefore not possible to accurately determine

whether these fluctuated over time. Although emotion perception and theory of mind abilities have been reported to not significantly differ across course of the illness progression (Green et al., 2012), it should be noted that these assessments were not undertaken in the midst of an acute phase. Furthermore, Horan et al. (2012) identified that small-to-medium improvements on some measures of social cognition were associated with general clinical improvement, suggesting that social cognition deficits and symptomatology may not be fully independent. Given the ethical issues that assessment during an acute psychotic episode could present, it is unclear to what extent this could be explored further. In the context of this study, there would be additional ethical implications to consider regarding the appropriateness of asking an individual to undertake such assessments shortly after the potential trauma of committing an act of violence (e.g. see Papanastassiou et al., 2004).

3.5.2.5 Use of a self-report measure of empathy.

The use of a self-report measure such as the IRI has some evident limitations in that an individual with limited perspective-taking ability may not appreciate that they are limited in this ability. In future studies the use of this measure could therefore be supplemented by a rating by others on each of the subscales; although the demands of this would need to be balanced with the challenges of recruitment.

However, a strength of the use of a self-report measure is that it enables the participant to provide a report of the level of empathic concern they are able to internally experience – even though in some circumstances this may not be generated due to other factors involved, as proposed by Marshall & Marshall (2011)'s model of empathy. This model suggests that an individual may not experience empathy for another's situation, not due to an inability to recognise another's distress, but relating to a dislike of the person concerned or experiencing excessive personal distress triggered by observing the situation. The IRI subscale of 'personal distress' therefore links in well with this model, as it allows an

understanding of the individual's experience of this factor which may impede the generation of an empathic response (Marshall & Marshall, 2011).

On balance, the IRI was therefore considered an appropriate tool for use in this study. Additional measures involving others' ratings of an individual's demonstrated empathic responses could enhance future studies.

3.5.2.6 Exclusion criteria

The selected exclusion criteria consisted of variables that would clearly impact upon the study's findings, which were deemed to not be prevalent in the majority of the population studied. In order to not excessively narrow the pool of potential participants, assessments were undertaken to identify the presence of other variables that were likely to be prevalent within the population of interest but which could impact on social cognition ability, rather than setting these as exclusion criteria. This meant that the sample in the study was reflective of their clinical population, but any between-group differences in the distribution of participants with these variables could be identified and controlled for. This improved on many studies which appear to have failed to control for the potential impact of personality disorder, ASD and/or depression on social cognition abilities (Abu-Akel & Abushua-leh, 2004; Majorec et al., 2009; Silver et al., 2005). The high prevalence of participants in both groups whose score on the IPDE screening questionnaire indicated the potential presence of one or more personality disorders suggests that inclusion of participants with a personality disorder was appropriate, as to exclude patients with a personality disorder would not have reflected the clinical reality of this population.

3.6 Conclusions

Unfortunately the hypotheses of this study could not be reliably addressed, as the study was inadequately powered due to encountering substantial difficulty

recruiting participants. This highlights a key issue for consideration during the development of similar studies in this field.

Whilst many factors may contribute to an individual committing violence to others, should social cognition deficits be found to be predictive of this, identification of this would be useful in many respects. Firstly, this would highlight an area to consider when assessing the risk to others that an individual may pose. In some individual cases, this may have been a pertinent feature and if so, awareness of this could help those who have undertaken or experienced acts of violence to understand what may have contributed to this. This would be helpful given the trauma such experiences entail, for both the victim and those who care about them, but in many cases those who have committed the act of violence too (Gray et al., 2003). Subsequent amelioration of these deficits would clearly then be useful in reducing risk and improving community functioning (Fett et al., 2011).

The strengths of this study's design could be utilised in future studies to build upon existing knowledge in this area. Where feasible, further exploration of this area would help increase understanding of the role of social cognition deficits in schizophrenia and violent offending. If people with schizophrenia with a history of violence have greater deficits in their social cognition abilities than those without a history of violence, this would highlight that these abilities could be assessed and included as part of a thorough risk assessment. It would also identify a key area for intervention, given that various social cognition training programmes have been found to improve facial affect recognition (Statucka & Walder, 2013) and theory of mind abilities (Langham et al., 2014) in people with schizophrenia.

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4 Supplementary Methods Chapter

This supplementary methods chapter outlines the supplementary hypotheses of the empirical study, provides details of analyses that had been planned to address these and reports the sample size required for each as calculated by a-priori power analyses.

4.1 Supplementary hypotheses

In addition to the key primary and secondary hypotheses outlined in section 3.2.5, the following hypotheses were also planned to be addressed through this study.

- i) An individual with schizophrenia's facial affect recognition ability will have predictive validity for their history of violence (with the former coded based on classification of overall PoFA performance and the latter rated on the modified "Rating from previous record" VRS subscale).*
- ii) An individual with schizophrenia's theory of mind ability will have predictive validity for their history of violence (with the former coded based on classification of performance on the 1st and 2nd order false belief tests and faux pas detection on the Faux Pas test, with the latter rated on the modified "Rating from previous record" VRS subscale).*
- iii) There will be a significant difference between the SHV and LNHV groups in their self-reported empathy (as measured by scores on each of the subscales of the IRI).*
- iv) There will be a positive correlation between participants' facial affect recognition ability and self-reported empathy (as measured by classification of performance on the PoFA and scores on the IRI subscales, particularly Empathic Concern and Perspective Taking).*

- v) Participants' self-reported empathy will have predictive validity for their history of violence (*respectively measured by scores on subscales of the IRI and rating on the modified "Rating from previous record" VRS subscale*).

4.2 Planned analyses

The scoring and interpretation of measures used is outlined in Appendix F. Prior to undertaking the following analyses, it was planned that the 'substantial history of violence' (SHV) and 'low/no history of violence' (LNHV) groups would be compared to see whether they significantly differed on the assessments used to identify potential confounding variables.

It was planned that if differences were identified, decisions would then be taken as to whether to statistically control for these using an Analysis of Covariance (ANCOVA) for the primary analysis.

4.2.1 Analyses A: Comparing SHV and LNHV groups on facial affect recognition and theory of mind abilities.

Please refer to section 3.3.7 in the main empirical study article for details of these analyses, designed to address the primary and secondary hypotheses.

4.2.2 Analysis B: Exploring the predictive ability of facial affect recognition and theory of mind abilities on history of violence.

This analysis is to address supplementary hypotheses *i*) and *ii*). It was planned that sequential multiple regression would be undertaken to identify how much facial affect recognition and theory of mind abilities (i.e. predictor variables) account for the variance of severity of violence (i.e. the criterion variable) within participants. This would be run by ranking the severity of violence using the 0-4 modified

violence rating scale (see Appendix E). The 'normal' and 'impaired' outcomes for facial affect recognition would be coded as '1' and '0' respectively. In order to reduce the number of individual predictor variables (which would increase the sample size required), performance on the theory of mind tests was planned to be ranked ordinally as follows:

0 = 'impaired' on all theory of mind tests

1 = 'normal' on 1st order theory of mind test, 'impaired' on 2nd order and advanced theory of mind tests

2 = 'normal' on 1st and 2nd order theory of mind tests, 'impaired' on advanced theory of mind test

3 = 'normal' on all theory of mind tests

The use of multiple regression would allow a model to be created showing what predictive value the outcomes of certain measures have for severity of historical violence. It is important to note that causality could not be assumed from this, as the predictive values found could be influenced by other variables that have not been measured in the study.

Sequential multiple regression was chosen as this would allow the predictor variables to be entered in order, in line with Marshall (1995)'s model of empathy. Mediation analysis could also be undertaken if required (Pearl, 2012).

Using the sample size calculation formula outlined by Tabachnik & Fidell (1996), to undertake a multiple regression using the two predictor variables of facial affect recognition and theory of mind ability, a total sample size of 66 for a medium effect size would be required. Including one or two of the control measures as predictor variables would raise the required sample size to 74 or 82 respectively. If large effect sizes were detected, the sample size required would be lower; Soper's (2012) a-priori

sample size calculator reports this to be 31, 36 or 39 respectively for two, three or four predictor variables.

4.2.3 *Analysis C: Differences between groups in self-reported empathy.*

This analysis is to address supplementary hypothesis *iii*). For each of the four subscales of the IRI, it was planned that any differences between the SHV and LNHV groups would be identified through use of a Student's independent samples *t*-test. This would be possible as the subscales have interval scores. For a two-tailed *t*-test with a medium effect size ($d=0.5$), where $\alpha=0.05$, a sample size of 128 (64 per group) would be required to achieve power of 0.8 (Erdfelder *et al.*, 1996). If the distribution of the data collected failed to meet the assumptions for use of this parametric test, it was planned that the nonparametric equivalent (the Mann-Whitney U) would be used instead. Clark-Carter (2004) has recommended that to calculate the sample size required for a Mann-Whitney U, the sample size for the *t*-test that would be used (if the data were parametric) should be multiplied by 1.05. Therefore, for the Mann-Whitney U a sample size of 135 would be required. For an effect size of $d=0.6$ the minimum required sample size would be 90 for a *t*-test or 95 for a Mann-Whitney U, or 52 for a *t*-test or 55 for a Mann-Whitney U if a large effect size of 0.8 was achieved (Soper, 2012). As with analysis A, if any control measures needed to be controlled for, an ANCOVA would instead be undertaken, resulting in a lower sample size being required (Borm *et al.*, 2007).

4.2.4 *Analysis D: Correlation between facial affect recognition and self-reported empathy*

This analysis is to address supplementary hypothesis *iv*). A biserial correlation was planned to be undertaken to explore whether facial affect recognition ability corresponds with each of the empathy subscales.

To explore the relationship between theory of mind ability and self-reported empathy, the theory of mind ability would be ranked on a scale of 0-3 as previously described. For this analysis, a two-tailed Pearson's Product Moment correlation would be undertaken (Clark-Carter, 2004). A sample size of 90 would be required to achieve power of 0.82 for the two-tailed Pearson's Product Moment correlation, for a medium effect size ($r=0.3$), or 30 for a large effect size ($r=0.5$) (Soper, 2012).

4.2.5 Analysis E: Predictive ability of empathy on history of violence

This analysis is designed to address supplementary hypothesis *v*). Multiple regression was planned to be undertaken, using any subscales of the IRI for which a significant between-group difference was identified through Analysis C. If all four subscales were used, a sample size of 82 would be required if there was a medium effect size (Tabachnik & Fidell, 1996) or 39 for a large effect size (Soper, 2012). Inclusion of the scores on two of the control measures as predictor variables would increase this required sample size to 98 (medium effect size) or 46 (large effect size).

4.2.5.1 Minimum required sample size

At the time of the study's design, there was a lack of research in the areas covered by the supplementary hypotheses. This meant it was not possible to predict what size of effect might be found. If medium effect sizes were found for all, a sample size of 98 would enable all of the hypotheses to be addressed with adequate power.

It was however recognised that recruitment of this number of participants may prove difficult. It was considered most important to address the study's primary hypothesis. As research linked to this area (as outlined in section 3.3.7 of the main empirical study) had suggested a large effect size may be present, this was utilised in the power calculation for the analysis planned to address this hypothesis. Undertaking this calculation identified that a sample size of 32 would be required

for this hypothesis to be sufficiently powered. If large effect sizes existed in relation to the secondary hypothesis and supplementary hypothesis D, these would also enable the analyses addressing these to be adequately powered. This was considered satisfactory in addressing the key areas of the study and so was accepted as a planned *minimum* sample size.

4.3 Alternative data analyses

There are additional ways in which the data collected for this study could be analysed. Grouping together all participants recruited to the study, as a group of males aged 21 – 66 with a diagnosis of schizophrenia, would enable the exploration of the following alternative areas of potential interest:

1. The data collected could be used to test the initial stages of Marshall & Marshall (2011)'s theoretical model of empathy, or all of the earlier and simpler three-stage model by Marshall et al. (1995). This would involve exploring whether performance on the social cognition measures used (PoFA, 1st and 2nd order false belief tasks and Faux Pas detection task) is predictive of self-reported empathy, as reported on the IRI.

To do so would involve undertaking a sequential multiple regression, in order to enter first the scores from the PoFA (assessing facial affect recognition ability, the first stage of the model) and then the scores relating to theory of mind ability (the second stage of the model, incorporating performance on the 1st and 2nd order false belief tasks and the Faux Pas detection task) as predictor variables. This would be run for each of the criterion variables, which would be the sub-scales on the IRI – with Empathic Concern and Perspective Taking considered of particular relevance.

Using a basic formula exploring solely the proportion of variance accounted for (rather than exploring the statistical significance), the minimum sample size would be 82 if all of the social cognition measures were included as predictor variables, or 66 if just PoFA performance and one of the theory of mind measures included as predictor variables (Clark-Carter, 2010). In either case, the sample size recruited in this study is insufficient to run the regression with adequate power.

2. Performance on the aforementioned measures of facial affect recognition and theory of mind, along with levels of self-reported empathy, could be correlated with the presence or severity of positive and negative symptoms of schizophrenia, as assessed using the PECC. This could help explore whether difficulties in these areas of social cognition are related to symptom presence or severity.

This area of analysis was not undertaken in this study, as this would move away from the original hypotheses of the study and the analyses that were planned a-priori. It was also recognised that participants had only provided consent to participate in the study as originally planned.

5 Supplementary Results Chapter

This chapter presents the results from running some of the statistical analyses outlined in the Supplementary Methods chapter. The descriptive statistics presented in the main article are not repeated here. It is acknowledged that the analyses were insufficiently powered and hence are presented separately for interest, with a recommendation that outcomes are interpreted with caution.

5.1 Comparing groups on demographic and control variables

5.1.1 Age

The mean ages of the SHV and LNHV groups were compared to see if these differed significantly. Visual inspection of histograms and Q-Q plots of the distribution of ages in each group suggested that there was some deviation from the normal distribution, but that this was not excessive. Calculation of the skewness and kurtosis ratios for each group (Weinberg & Abramowitz, 2002) showed that the distributions were not excessively skewed or kurtotic (Cramer & Howitt, 2004). Lastly the Shapiro-Wilk test of normality (Shapiro & Wilk, 1965) was run; this test was selected due to its greater power as compared to other tests of normality (Razali & Wah, 2011), although it is acknowledged that its power is still low for the small sample sizes in this study. For each group, $p > 0.05$ (SHV group: $W=0.926$, $p=0.185$; LNHV group: $W=0.874$, $p=0.283$). It was therefore concluded that the ages of participants were approximately normally distributed in each group.

The mean age of each group was therefore compared using a Student's t test for two independent samples, as the assumptions for use of this test were met. This was not

significant ($t=-1.315$, $p=0.203$), confirming that the mean age of participants did not differ significantly by group.

5.1.2 Control measures

For each of the measures used to assess the presence of potentially confounding variables, a categorical outcome was determined, as detailed in Appendix F. The prevalence of each of the potential confounding variables in the SHV and LNHV groups was compared, as assessed through use of the control measures. For each of these comparisons, the requirements for use of Pearson's *chi-squared* that "*none of the expected frequencies should be less than 1, and that no more than 20% of the expected frequencies should be less than 5*" (Cochran, 1952; in Sheskin, 2007, p621) were considered. For each comparison, one or both of these requirements were broken, so Fisher's exact test was applied instead, as it does not share this requirement. This does have an assumption of fixed marginal frequencies, but it has been noted that in practice it is used when neither the row nor column sums have been predetermined (Daniel, 1990; in Sheskin, 2007, p632). The outcomes of these comparisons are presented in Table 5.1.

Table 5.1. Outcomes of comparisons between SHV and LNHV groups on presence of control variables.

Variable	<i>p</i> value from Fisher's two-tailed test
No. ptps with potential personality disorder(s)	1.000
No. ptps with potential presence of undiagnosed ASD	0.411
No. ptps with clinically significant levels of depression	0.585
No. ptps experiencing positive symptoms of schizophrenia	0.323
No. ptps experiencing negative symptoms of schizophrenia	0.135
No. ptps experiencing anxiety	1.000

These comparisons showed that the proportion of participants with each of these variables did not significantly differ between groups. It was therefore considered unlikely that these would confound the outcomes on the experimental measures, so the analyses could be run as planned without the need to control for these variables.

5.2 Outcomes from analyses

The following outcomes must be interpreted with caution. None of the analyses were adequately powered and where comparisons were undertaken between SHV and LNHV groups, there was a notable imbalance in sample size which further reduces the reliability of outcomes found. Therefore, even where significant results were reported, their validity remains questionable.

5.2.1 Analyses

5.2.1.1 Analysis A: Comparing SHV and LNHV groups on facial affect recognition and theory of mind abilities.

For each of the social cognition measures used, a categorical outcome was determined of “normal” or “impaired”, as detailed in Appendix F. Given the categorical nature of these outcomes, parametric tests could not be used. The aforementioned assumptions required for a Pearson’s *chi-squared* test, were not met for any of these outcomes and so Fisher’s exact test was used instead. The outcomes of these comparisons are presented in Table 5.2.

i) Facial affect recognition

The groups did not differ significantly in their overall facial affect recognition ability. When individual emotion recognition abilities were compared, the groups only **differed significantly in their ability to identify sadness**. While all participants in the LNHV group were classed as performing within the “normal” range for sadness recognition, over half (58%) of the SHV group were classed as “impaired”. Given the repeated comparisons and post-hoc nature of these individual emotion recognition comparisons, it could however be considered that a

correction should be made for the inflated risk of a Type I error. When a Bonferroni correction was made to the level of α for the six additional comparisons made, $\alpha=0.008$ (Clark-Carter, 2010, p264). Use of the Bonferroni correction for a large number of tests can be conservative, but use of the less conservative Holm's sequential adjustment (Holm, 1979) did not alter this as only one significant result was found. Therefore, after Bonferroni correction the difference between groups on recognition of sadness is no longer considered significant. The moderate association of sadness affect recognition ability and history of violence was however found to be significant by calculation of Cramer's V ($V=0.495$, $p=0.020$) (Dancey & Reidy, 2004, p171).

Table 5.2. Comparison of proportion of participants in the SHV and LNHV groups scoring within the normal range for each of the social cognition measures.

Area of social cognition	<i>p</i> value from Fisher's two-tailed test
<i>Facial affect recognition:</i>	
Overall facial affect recognition ability	1.000
<i>Individual emotion recognition:</i>	
Happiness	1.000
Sadness	0.040*
Anger	1.000
Disgust	1.000
Fear	0.609
Surprise	0.411
<i>Theory of mind:</i>	
1 st order false belief task	1.000
2 nd order false belief task	0.613
Faux pas detection	0.135

* Significant where $\alpha=0.05$, but not after Bonferroni correction (where $\alpha=0.008$)

ii) Theory of mind

The proportion of participants correctly answering the first- and second-order false belief tests did not significantly differ between the SHV and LNHV groups.

Although the proportion of participants scoring within the normal range for faux pas detection was lower in the LNHV group than the SHV group, this difference was not statistically significant.

5.2.1.2 *Analysis B: Exploring the predictive ability of facial affect recognition and theory of mind abilities on history of violence.*

This analysis was not undertaken as originally planned, due to the inadequate sample size for a sequential multiple regression, along with the lack of significant differences between groups on the various measures of social cognition abilities.

5.2.1.3 *Analysis C: Differences between groups in self-reported empathy.*

The normality of the distribution of participants' scores on each of the subscales of the IRI was checked through visual inspection of histograms and Q-Q plots of the scores, calculation of skewness and kurtosis ratios and use of the Shapiro-Wilk test for normality. The outcomes of these checks are presented in Table 5.3. This process showed that the distribution of scores on the Fantasy, Perspective Taking and Personal Distress subscales did not significantly differ from normality and so met the assumptions for use of the Student's *t* test for two independent samples. Running this test for each of these three subscales showed that the SHV and LNHV groups did not significantly differ in their scores on each of these subscales (Fantasy: $t=-1.146$, $p=0.265$; Perspective Taking: $t=0.593$, $p=0.582$; Personal Distress: $t=-1.948$, $p=0.066$).

Table 5.3. Outcomes of normality checks for each of the IRI subscales

IRI Subscale	Skewness ratio	Kurtosis ratio	Shapiro-Wilk
<i>Fantasy</i>			
SHV group:	-0.296	-0.518	W=0.980, $p=0.956$
LNHV group:	-1.373	1.016	W=0.917, $p=0.508$
<i>Empathic Concern</i>			
SHV group:	1.964	1.358	W=0.905, $p=0.083$
LNHV group:	-1.165	0.101	W=0.907, $p=0.451$
<i>Perspective Taking</i>			
SHV group:	0.329	-1.077	W=0.946, $p=0.403$
LNHV group:	-0.674	0.260	W=0.955, $p=0.774$
<i>Personal Distress</i>			
SHV group:	-0.036	-0.949	W=0.955, $p=0.545$
LNHV group:	-0.069	-0.181	W=0.981, $p=0.940$

Calculation of the skewness ratio for the SHV group's Empathic Concern scores showed that this fell outside the 95% confidence interval for the normal distribution. This meant that the assumptions for use of the Student's *t* test were not met for this scale, so the Mann-Whitney *U* Test was used instead. This showed that **the distribution of scores for participants in each group was significantly different for the empathic concern subscale** ($p=0.022$). Visual inspection of a histogram of the scores showed participants in the SHV group tended to have lower scores on this subscale than those in the LNHV group.

5.2.1.4 *Analysis D: Correlation between social cognition abilities and self-reported empathy.*

i) Correlation between facial affect recognition and self-reported empathy.

A correlation of the relationship between facial affect recognition ability and empathic concern was undertaken. As previously found, the distribution of performance on the EC subscale was not normal, so the assumptions for use of the Pearson's *r* were not fulfilled (Dancey & Reidy, 2004, p170). Therefore the non-parametric equivalent, a Spearman's rho, was used instead. The relationship between the two was not significant ($r_s=0.341$, $p=0.121$). The correlations for each of the other subscales with facial affect recognition ability were also not significant (FS: $r_s=0.105$, $p=0.642$; PT: $r_s=0.249$, $p=0.249$; PD: $r_s=0.124$, $p=0.582$).

ii) Correlation between theory of mind ability and self-reported empathy.

It was not possible to assign ordinal rankings to participants on the basis on their performance on theory of mind tests, because contrary to expected, some participants who did not answer the second-theory of mind test correctly then went on to score within the "normal" range for the faux pas test. Therefore the performance on each test was separately correlated with each of the empathy subscales. As the theory of mind first and second order tests produced dichotomous

variables, whilst the IRI scores are interval, a point-biserial correlation coefficient was appropriate (Sheskin, 2007, p139). This did involve an assumption that the underlying distribution of the IRI scores was normal. However, whilst the distribution of EC scores for the SHV group was positively skewed, as previously reported, use of the Shapiro-Wilk test for normality did not find the scores for each group on each of these subscales differed significantly from a normal distribution (see Table 3). Given the lack of viable alternatives due to the level of measurement of the data, the point-biserial correlation coefficient was therefore used.

With the theory of mind performance being used as a dummy variable (i.e. 1="normal" and 0="impaired"), the equation for the point-biserial correlation coefficient is the same as that for a Pearson product-moment correlation (Sheskin, 2007, p1297).

Undertaking this found that none of the IRI subscales had a significant correlation with first-order theory of mind test performance (FS: $r_{pb}=0.318$, $p=0.075$; EC: $r_{pb}=0.148$, $p=0.256$, PT: $r_{pb}=-0.009$, $p=0.484$, PD: $r_{pb}=0.225$, $p=0.157$).

There was a **significant correlation found between performance on the second-order theory of mind test performance and scores on the Perspective Taking subscale** of the IRI ($r_{pb}=0.404$, $p=0.031$), which by Cohen's guidelines equates to a medium effect size (Clark-Carter, 2010, p293). Visual exploration of the data showed that if a participant's performance on the second-order theory of mind test was classed as "normal", they tended to have a higher score on the Perspective Taking subscale of the IRI. There was no significant correlation found between second-order theory of mind test performance and scores on the other three IRI subscales (FS: $r_{pb}=0.344$, $p=0.059$, EC: $r_{pb}=0.160$, $p=0.238$; PD: $r_{pb}=0.107$, $p=0.317$).

None of the IRI subscales had a significant correlation with faux pas performance (FS: $r_{pb} = 0.45$, $p = 0.841$; EC: $r_{pb} = -0.311$, $p = 0.158$; PT: $r_{pb} = 0.012$, $p = 0.957$; PD: $r_{pb} = 0.011$, $p = 0.961$).

5.2.1.5 Analysis E: Predictive ability of empathy on history of violence

Due to inadequate sample size and the finding that the SHV and LNHV groups differed on only one subscale of the IRI, the planned multiple regression exploring the predictive ability of empathy on history of violence was not undertaken.

5.2.2 Additional analyses

Additional correlations were undertaken to further explore the relationship between participants' performance on different theory of mind measures. Due to their categorical outcomes, the association between performances on each of these measures was calculated with use of the contingency coefficient (Skessin, 2007, p139 & 657), as shown in Table 5.4. This showed that the performance on these measures were not significantly associated with one another.

Table 5.4. Matrix of contingency coefficients showing association between social cognition variables.

	Facial affect recognition	First order false belief test	Second order false belief test	Faux pas detection
Facial affect recognition		C=0.254, p=0.219	C=0.052, p=0.806	C=0.166, p=0.429
First order false belief test	C=0.254, p=0.219		C=0.277, p=0.176	C=0.232, p=0.262
Second order false belief test	C=0.052, p=0.806	C=0.277, p=0.176		C=0.120, p=0.571
Faux pas detection	C=0.166, p=0.429	C=0.232, p=0.262	C=0.120, p=0.571	

5.3 Summary of findings from statistical analyses

These analyses were run with the acknowledgement that their outcomes must be interpreted with caution due to the small and uneven sample sizes. Running the analyses did identify a few statistically significant results; given the small sample size it is possible that these may be as a result of a type I error (Christley, 2010).

Whilst taking this into account, Analysis A did suggest that the trend observed for the SHV group to have greater deficits in recognising sadness could be substantiated were a larger sample size available. Although a significant difference did not withstand Bonferroni correction, its presence where $\alpha=0.05$ means this could be considered as a preliminary finding, to be confirmed through further research. It is unclear whether other observed trends of differences between the two groups in their social cognition abilities, as outlined in the main empirical study, would also be statistically significant were an adequate sample size used. This potential deficit could be theorised to result in people not moderating their violent actions due to a lack of accurate feedback of their impact on others (e.g. Blair, 1995).

Another point of interest was the finding that the SHV group reported experiencing less empathic concern than the LNHV group. This would link to the theories that the experience of empathy is required to inhibit violence (Blair, 1995; Marshall *et al.*, 1995; Marshall & Marshall, 2011).

The significant correlation found between performance on the second-order theory of mind test performance and scores on the Perspective Taking subscale makes intuitive sense and suggests a link between the two, which would appear to provide some support for the stepwise models of empathy (Marshall *et al.*, 1995; Marshall & Marshall, 2011).

These outcomes are clearly tentative given the sample sizes used, however the analyses could be used in future studies if the recruitment of an adequate sample size for both groups could be achieved.

6 References for thesis

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7.1 Appendix A - Author guidelines for the British Journal of Psychiatry

INSTRUCTIONS FOR AUTHORS

Introduction

The *British Journal of Psychiatry* is published monthly by [The Royal College of Psychiatrists](#). The *Journal* publishes original work in all fields of psychiatry. Manuscripts for publication should be submitted online via <http://submit-bjp.rcpsych.org>.

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All submissions to the *Journal* (including editorials and letters to the Editor) require a declaration of interest. This should list fees and grants from, employment by, consultancy for, shared ownership in, or any close relationship with, at any time over the preceding 36 months, an organisation whose interests may be affected by the publication of the paper. It should also list any non-financial associations or interests (personal, professional, political, institutional, religious, or other) that a reasonable reader would want to know about in relation to the submitted work. This pertains to all the authors of the study, their spouses or partners and their children (aged under 18). We recommend use of the [disclosure form](#) developed by the International Committee of Medical Journal Editors for this purpose.

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Structure of manuscripts

Papers

A structured abstract not normally exceeding 150 words should be given at the beginning of the article, incorporating the following headings: Background; Aims; Method; Results; Conclusions; Declaration of interest. The abstract is a crucial part of the paper and authors are urged to devote some care to ensuring that all the important findings are within the word limit.

Introductions should normally be no more than one paragraph; longer ones may be allowed for new and unusual subjects. This should be followed by Method, Results and Discussion sections. The Discussion should always include limitations of the paper to ensure balance. Use of subheadings is encouraged, particularly in Discussion sections. A separate Conclusions section is not required.

The article should normally be between 3000 and 5000 words in length (excluding references, tables and figure legends) and normally would not include more than 25 essential references beyond those describing statistical procedures, psychometric instruments and diagnostic guidelines used in the study. All large tables (exceeding half a *Journal* page) will be published only in the online version of the *Journal* (see Online data supplements, below). Authors are encouraged to present key data within smaller tables for print publication. This applies also to review articles and short reports.

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Review articles should be structured in the same way as regular papers, but the length of these may vary considerably, as will the number of references. Systematic reviews are preferred and narrative reviews will be published only under exceptional circumstances. Reviews done for the Cochrane Collaboration, the National Institute for Health and Clinical Excellence and other groups likely to be published, or already published, elsewhere, should have the submitted paper accompanied by the latest version of the parent review and its status so that an informed decision can be made about the added value of the submitted paper.

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Short reports require an unstructured summary of one paragraph, not exceeding 100 words. The report should not exceed 1200 words (excluding references, tables and figure legends) and contain no more than one figure or table and up to 10 essential references beyond those describing statistical procedures, psychometric instruments and diagnostic guidelines used in the study. Short reports will not exceed two printed pages of the *Journal* and authors may be required to edit their report at proof stage to conform to this requirement. This may be necessary even if the report does not exceed 1200 words if the figure or table is unduly large.

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Editorials require an unstructured summary of one paragraph, not exceeding 50 words. Editorials should not exceed 1500 words and may contain no more than one figure or table and up to 10 essential references. Editorials may only exceed two printed pages in length at the Editor's discretion. A good-quality photograph of the lead author for publication alongside the editorial must be submitted with the manuscript, along with brief biographical details (up to 25 words) for all authors.

Reappraisal

This is a section following the structure of Editorials but with up to 15 essential references. These articles are mainly commissioned by the Editor and are concerned with well-known subjects in psychiatry which are going through a period of controversy or re-evaluation. Reappraisals are intended to give a long-term balanced perspective on the subject based on the latest evidence.

Debates

Authors may submit proposals for In Debate articles, providing a brief (one paragraph) outline of the issue to be debated together with the proposed motion. They may also suggest an opponent for the debate. Two debaters have three rounds of debate (1-2-1-2-1-2), responding to each other after each round. Each author may use up to 2000 words and 15 references, divided as they wish between their three rounds. A short introduction will be provided by the Debates Editors post-acceptance. In Debate articles not adhering to this format will not usually be considered.

References

Authors are responsible for checking all references for accuracy and relevance in advance of submission. Reference lists not in the correct style will be returned to the author for correction. From January 2008, all references should be numbered in the order in which they

appear in the text and listed at the end of the article using the Vancouver style (see below), in which the names and initials of all authors are given after the appropriate reference number. If there are more than six authors, the first six should be named, followed by 'et al.'. The authors' names are followed by the full title of the article; the journal title abbreviated (in italics) according to the style of Index Medicus; the year of publication; the volume number (in bold type); and the first and last page numbers. References to book or book chapters should give the titles of the book (and the chapter if selected), names of any authors, name of publisher, names of any editors, and year. Examples are shown below.

1 Kapusta ND, Etzersdorfer E, Krall C, Sonneck G. Firearm legislation reform in the European Union: impact on firearm availability, firearm suicide and homicide rates in Austria. *Br J Psychiatry* 2007; **191**: 253-7.

2 Thornicroft GJ. *Shunned: Discrimination Against People with Mental Illness*. Oxford University Press, 2006.

3 Casey P. Alternatives to abortion and hard cases. In *Swimming Against the Tide; Feminist Dissent on the Issue of Abortion* (ed AB Kennedy): 86-95. Open Air Books, 1997.

4 Lancet. Burnished or burnt out: the delights and dangers of working in health (editorial). *Lancet* 1994; **344**: 1583-4.

5 Pharmaceutical Research and Manufacturers of America (PhRMA). *PhRMA Guiding Principles on Direct to Consumer Advertisements About Prescription Medications*. PhRMA, 2005. <http://www.phrma.org/publications/policy//2005-08-02.1194.pdf>

6 Soni SD, Mallik A, Mbatia J, Shrimankar J. Late paraphrenia (letter). *Br J Psychiatry* 1988; **152**: 719-20.

7 Viding E, Frick P, Plomin R. Aetiology of the relationship between callous-unemotional traits and conduct problems in childhood. *Br J Psychiatry* 2007; **190** (suppl 49): s33-8.

Personal communications need written authorisation (email is acceptable); they should not be included in the reference list. Unpublished doctoral theses may be cited (please state department or faculty, university and degree). No other citation of unpublished work, including unpublished conference presentations, is permissible.

Tables

Tables should be numbered and have an appropriate heading. The tables should be mentioned in the text but must not duplicate information. The heading of the table, together with any footnotes or comments, should be self-explanatory. The desired position of the table in the manuscript should be indicated. Do not tabulate lists, which should be incorporated into the text, where, if necessary, they may be displayed.

Authors must obtain permission from the original publisher if they intend to use tables from other sources, and due acknowledgement should be made in a footnote to the table.

Figures

Figures should be clearly numbered and include an explanatory legend. Avoid cluttering figures with explanatory text, which is better incorporated succinctly in the legend. 3-D effects should generally be avoided. Lettering should be parallel to the axes. Units must be clearly indicated and should be presented in the form quantity (unit) (note: 'litre' should be spelled out in full unless modified to ml, dl, etc.). All figures should be mentioned in the text and the desired position of the figure in the manuscript should be indicated.

Authors must obtain permission from the original publisher if they intend to use figures from other sources, and due acknowledgement should be made in the legend.

Colour figures may be reproduced if authors are able to cover the costs.

Statistics

Methods of statistical analysis should be described in language that is comprehensible to the numerate psychiatrist as well as the medical statistician. Particular attention should be paid

to clear description of study designs and objectives, and evidence that the statistical procedures used were both appropriate for the hypotheses tested and correctly interpreted. The statistical analyses should be planned before data are collected and full explanations given for any *post hoc* analyses carried out. The value of test statistics used (e.g. *t*, *F*-ratio) should be given as well as their significance levels so that their derivation can be understood. Standard deviations and errors should not be reported as \pm but should be specified and referred to in parentheses.

Trends should not be reported unless they have been supported by appropriate statistical analyses for trends.

The use of percentages to report results from small samples is discouraged, other than where this facilitates comparisons. The number of decimal places to which numbers are given should reflect the accuracy of the determination, and estimates of error should be given for statistics.

A brief and useful introduction to the place of confidence intervals is given by Gardner & Altman (1990, *British Journal of Psychiatry*, **156**, 472-474). Use of these is encouraged but not mandatory.

Authors are encouraged to include estimates of statistical power where appropriate. To report a difference as being statistically significant is generally insufficient, and comment should be made about the magnitude and direction of change.

Randomised controlled trials

The *Journal* requires authors to submit a completed checklist and flowchart in accordance with the appropriate [CONSORT guidelines](#). The registration details of the trial and a flow chart illustrating the progress of participants through the trial (CONSORT diagram) must be included in the submitted manuscript.

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Observational/epidemiological studies

For reports of epidemiological research, please ensure that the appropriate [STROBE checklist](#) is followed.

Qualitative research

The *Journal* welcomes submissions of reports of qualitative research relevant to the scope of the *Journal*. These manuscripts will be evaluated in terms of design, conduct and reporting of the study, which need to be of sufficient quality and merit to warrant inclusion in the *Journal*. The Editor recognises that the term 'qualitative research' encompasses diverse methods underpinned by various epistemological or theoretical frameworks. Accordingly, manuscripts will be evaluated on the basis of the appropriateness of the selected framework to the enquiry, the internal coherence of the report and its adherence to quality criteria consistent with the methodology and method as follows:

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The epistemological underpinnings and/or theoretical framework is made explicit and applied consistently

Study design and method

The research goal is clearly articulated, justified with reference to literature, and placed in context

The approach matches the purpose of research and is justified

Methods of sampling, data collection, data management and analysis are explicit and consistent with methodology

Analytical and interpretative processes are described fully

Findings, discussion and implications

Findings represent the depth and breadth of data

Findings and interpretations are supported by the data

Direct quotations, exemplars or other data presentations are used judiciously in a way that illustrates the findings

Findings are presented in a way that is consistent with methodology, method and study aims

Authors are appropriately cautious about knowledge claims

Findings are explored theoretically and applications discussed

Process issues

The report provides an account of reflexive practice in keeping with the methodology

The review of the manuscript will determine whether the authors present their research in such a way that the reader can evaluate the relevance, credibility and applicability of the generated evidence.

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For further guidance, authors may refer to the [Royal College of Psychiatrists' house style guide](#).

Access to data

If the study includes original data, at least one author must confirm that he or she had full access to all the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. We strongly encourage authors to make their source data publicly available.

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The *Journal* recommends that all clinical trials are registered in a public trials registry.

Further details of criteria for acceptable registries and of the information to be registered are available at http://www.icmje.org/index.html#clin_trials. For reports supported by industry funds, this is a requirement for the paper to be considered for publication in the *Journal*.

Case reports and consent

If an individual is described, his or her consent must be obtained and submitted with the manuscript. Our [consent form](#) can be downloaded here. The individual should read the report before submission. If it is not possible for informed consent to be obtained, the report can be published only if all details that would enable any reader (including the individual or anyone else) to identify the person are omitted. Merely altering some details, such as age and location, is not sufficient to ensure that a person's confidentiality is maintained.

Contributors should be aware of the risk of complaint by individuals in respect of defamation and breach of confidentiality, and where concerned should seek advice. In general, case studies are published in the *Journal* only if the authors can present evidence that the case report is of fundamental significance and it is unlikely that the scientific value of the communication could be achieved using any other methodology.

Online data supplements

Material related to a paper but unsuitable for publication in the printed journal (e.g. large tables) may be published as a data supplement to the online *Journal* at the Editor's discretion. For very large volumes of material, charges may apply.

Abbreviations, units and footnotes

All abbreviations must be spelt out on first usage and only widely recognised abbreviations will be permitted.

The generic names of drugs should be used.

Generally, SI units should be used; where they are not, the SI equivalent should be included in parentheses. Units should not use indices: i.e. report g/ml, not gml⁻¹.

The use of notes separate to the text should generally be avoided, whether they be footnotes or a separate section at the end of a paper. A footnote to the first page may, however, be included to give some general information concerning the paper.

Materials, equipment and software

The source of any compounds not yet available on general prescription should be indicated. The version number (or release date) and manufacturer of software used, and the platform on which it is operated (PC, Mac, UNIX etc.), should be stated. The manufacturer, manufacturer's location and product identification should be included when describing equipment central to a study (e.g. scanning equipment used in an imaging study).

Proofs

A proof will be sent to the corresponding author of an article. Offprints, which are prepared at the same time as the *Journal* is printed, should be ordered when the proof is returned to the Editor. Offprints are despatched up to 6 weeks after publication.

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At any time up to 5 years after publication of research in the *Journal*, authors may be asked to provide the raw data.

7.2 Appendix B - Quality rating criteria developed for systematic review

i) Randomisation

Well addressed	<ul style="list-style-type: none"> Random allocation <i>and</i> concealment was undertaken for each of the treatment groups. A clear description of this procedure is provided.
Adequately addressed	<ul style="list-style-type: none"> It is reported that random allocation was undertaken for each of the treatment arms, but it is unclear exactly how this was undertaken or if concealment occurred.
Limitations	<ul style="list-style-type: none"> Random allocation to the experimental group was undertaken, but not to other treatment arms.
Not reported	<ul style="list-style-type: none"> The allocation procedure of participants to each of the treatment arms is not reported.
Not addressed	<ul style="list-style-type: none"> Random allocation to any of the treatment arms was not undertaken

ii) Blinding

Well addressed	<ul style="list-style-type: none"> It is clear how steps were taken to blind those administering the outcome measures as to which intervention the participant had received. No concerns are noted as to the effectiveness of this.
Adequately addressed	<ul style="list-style-type: none"> It is reported that those who administered the outcome measures were blinded as to the intervention the participant had received, however it is not clear how this was undertaken.
Limitations	<ul style="list-style-type: none"> It is reported that blinding was undertaken for some but not all of the treatment groups/assessments of relevance.
Not reported	<ul style="list-style-type: none"> It is not reported whether those administering the outcome measures were blinded as to the participant's treatment group.
Not addressed	<ul style="list-style-type: none"> The blinding of those administering the outcome measures was not undertaken.

iii) *Attrition*

Well addressed	<ul style="list-style-type: none"> The number of participants withdrawing from any of the treatment arms is provided, ideally with the reasons for this provided. Either there was no attrition; or where there has been attrition from the group receiving the experimental intervention, this has been accounted for in the analyses undertaken, for example by the use of intention to treat analyses.
Adequately addressed	<ul style="list-style-type: none"> The number of participants withdrawing from any of the treatment arms is provided. This has not been accounted for in the analyses undertaken, but it seems unlikely that this would change the findings of the study (e.g. because the attrition rate was low and/or there was a similar attrition rate in both the experimental and control groups).
Limitations	<ul style="list-style-type: none"> Attrition has occurred and has been reported, but has not been addressed by the analysis and it seems likely that this may have affected the findings of the study (i.e. due to a high attrition rate from the experimental group, particularly in comparison to the control group).
Not reported	<ul style="list-style-type: none"> Attrition rates are not reported and it is not possible to determine from the data provided whether attrition occurred.
Not addressed	<ul style="list-style-type: none"> It appears from the data presented (i.e. in results tables) that attrition occurred, but this was not reported in the text or figures and this does not appear to have been accounted for in the analyses undertaken.

iv) *Treatment fidelity - Attendance*

Well addressed	<ul style="list-style-type: none"> The attendance rate for the interventions has been reported and either is above 75% or has been adequately accounted for in the analyses undertaken.
Adequately addressed	<ul style="list-style-type: none"> The attendance rate for the interventions is above 75% or has been adequately accounted for in the analyses undertaken.
Limitations	<ul style="list-style-type: none"> The attendance rate for the experimental intervention is below 75% and has not been accounted for in the analyses undertaken
Not reported	<ul style="list-style-type: none"> The attendance rate for the experimental intervention has not been reported.
Not addressed	<ul style="list-style-type: none"> Appears that there may not have been 100% attendance, but this has not been reported.

v) *Treatment fidelity - training and monitoring*

Well addressed	<ul style="list-style-type: none"> Facilitators have received <i>specific</i> training to deliver the intervention, <i>and</i> The fidelity of the intervention provided has been monitored (e.g. through the use of supervision/recording sessions etc).
Adequately addressed	<ul style="list-style-type: none"> Facilitators have received <i>specific</i> training to deliver the intervention
Limitations	<ul style="list-style-type: none"> Deviations from the planned intervention occurred, which appear likely to have affected the findings of the study.
Not reported	<ul style="list-style-type: none"> It has not been reported whether any training to deliver the intervention or fidelity monitoring was undertaken.
Not addressed	<ul style="list-style-type: none"> It is reported that no training to deliver the intervention or fidelity monitoring was undertaken.

vi) *Replicability of intervention*

Well addressed	<ul style="list-style-type: none"> Detailed information (e.g. a manual) to allow this intervention to be replicated is available The intervention was either described clearly or a reference was provided for further information, such that a good understanding of what the intervention entailed could be gained. This would include details of the intervention, with the frequency, duration and modality (individual or group) provided. Where applicable, the size of the group (where applicable) and number of the facilitators was provided.
Adequately addressed	<ul style="list-style-type: none"> The intervention was either described clearly or a reference was provided for further information, such that a good understanding of what the intervention entailed could be gained. This would include details of the intervention, with the frequency, duration and modality (individual or group) provided. Where applicable, the size of the group (where applicable) and number of the facilitators was provided.
Limitations	<ul style="list-style-type: none"> Insufficient detail or links to information elsewhere was provided regarding the intervention, meaning it was unclear what it entailed.
Not reported	<ul style="list-style-type: none"> N/A as studies not reporting any intervention would not be included in this review.
Not addressed	<ul style="list-style-type: none"> N/A, as only studies involving an intervention were included in this review.

vii) *Internal validity – control of other confounding variables*

Well addressed	<ul style="list-style-type: none"> • A control/comparison group involving participants from the same population was used. • No significant differences were present between groups in their baseline performance on the theory of mind (ToM) measures. • Groups were compared for demographic and clinical (e.g. symptomatology) with the outcomes of this comparison reported. Either no significant differences on variables of likely relevance to outcome were identified, or any differences considered to be of <u>relevance</u> were adequately controlled for in analysis.
Adequately addressed	<ul style="list-style-type: none"> • A control/comparison group involving participants from the same population was used. • No significant differences were present between groups on baseline ToM measure. • Significant differences were present between groups in some demographic and/or clinical (e.g. symptomatology) variables. This was not controlled for but was not considered to have a substantial impact on the reliability of the study's findings.
Limitations	<ul style="list-style-type: none"> • A control/comparison group was used, but significant differences were present between groups on baseline ToM measures and/or clinical variables. These were not controlled for in the analysis and were considered likely to confound the outcomes of the study.
Not reported	<ul style="list-style-type: none"> • It was not reported whether a control/comparison group was used. • OR if a control/comparison group was utilised, no/insubstantial assessment of differences between groups at baseline was reported.
Not addressed	<ul style="list-style-type: none"> • No control/comparison group was used and no information regarding known (lack of) practice effects on the ToM measure for that population were reported, hence improvements on ToM measure post intervention could have been due to practice effects.

viii) *External validity*

Well addressed	<ul style="list-style-type: none"> • Within the constraints of this review's inclusion criteria (diagnosis of schizophrenia/schizoaffective disorder), the participants were reasonably representative of their population and were recruited from a general clinical setting for this population. • The exclusion criteria applied seemed reasonable and would not substantially undermine generalisability of findings by being too broad or narrow. • Participants opted to either take part in study or not (rather than one treatment arm vs another), thus removing potential for there being differences between those who took part in (for example) the TAU group compared to experimental group.
Adequately addressed	<ul style="list-style-type: none"> • Within the constraints of this review's inclusion criteria (diagnosis of schizophrenia/schizoaffective disorder), the participants were reasonably representative of their population, although may have been recruited from a more specialised clinical setting. • The exclusion criteria applied may have been slightly narrower or broader than ideal, but was not considered likely to notably undermine the generalisability of findings. • Participants may have opted in to one group but not another (e.g. opted not to participate but took part in waiting list control); information was provided regarding this.
Limitations	<ul style="list-style-type: none"> • Participants were clearly not representative of their population, due to excessively narrow or broad inclusion/exclusion criteria being used.
Not reported	<ul style="list-style-type: none"> • No information was reported regarding the inclusion/exclusion criteria.
Not addressed	<ul style="list-style-type: none"> • N/A

ix) Outcome measure

Well addressed	<ul style="list-style-type: none"> • Information or a reference has been provided, enabling a clear understanding to be gained of what at least one of the measures of ToM entails. • Measure has been used with people with schizophrenia, with differences found between those with schizophrenia and controls; where reported psychometric properties appear reasonable • At least one of the measures used appears an appropriate selection (it has good face validity).
Adequately addressed	<ul style="list-style-type: none"> • Information or a reference has been provided, enabling an adequate understanding to be gained of what at least one of the measures of ToM entails. • The standardisation of the measure with this population is less clear. • At least one of the measures used appears a reasonable selection.
Limitations	<ul style="list-style-type: none"> • It is reported that a ToM measure has been used, but insufficient information has been provided to identify the measure or understand what it entails <i>and/or</i> it is unclear if it adequately assesses ToM. • There are concerns regarding its appropriateness (i.e. it has poor face validity).
Not reported	<ul style="list-style-type: none"> • N/A as studies not reporting use of ToM measure would not be included for quality review.
Not addressed	<ul style="list-style-type: none"> • N/A as studies not using ToM measure would not be included for quality review.

x) *Power – sample size*

Well addressed	<ul style="list-style-type: none"> An <i>a priori</i> power calculation was undertaken to determine the required sample size and reported in the article. A sufficient sample size of participants completing both pre and post outcome measures was used to achieve power of 0.8, where alpha was 0.5 and using reasonable estimate of effect size, ideally based on existing literature in the field.
Adequately addressed	<ul style="list-style-type: none"> It was reported that adequate power for was achieved in the study, but details regarding this calculation were not provided.
Limitations	<ul style="list-style-type: none"> A power calculation was completed, but the sample size of participants at the end of the study was insufficient to meet this calculation. Or the sample size is reported to be a limitation to the study i.e. that its size was insufficient or that replication with a larger sample size is required.
Not reported	<ul style="list-style-type: none"> A power calculation was not reported.
Not addressed	<ul style="list-style-type: none"> Power calculation was not completed, or study did not have a sufficient sample size to meet the power calculation.

xi) *Analysis and reporting of analysis*

Well addressed	<ul style="list-style-type: none"> The statistical analyses undertaken provide meaningful results relating to ToM outcomes, which are clearly reported including provision of p-values and measure of effect sizes where appropriate for ToM outcomes.
Adequately addressed	<ul style="list-style-type: none"> Meaningful results allowing conclusions to be drawn regarding ToM are reported, but there may be less information provided regarding the analyses undertaken.
Limitations	<ul style="list-style-type: none"> There are limitations in the amount or detail of information reported regarding analyses relating to ToM outcomes, resulting in few or no meaningful conclusions being drawn. There may be concerns regarding the suitability of the analyses for the data.
Not reported	<ul style="list-style-type: none"> No information is reported regarding the analyses undertaken relating to the ToM measures and/ or the outcomes of these.
Not addressed	<ul style="list-style-type: none"> There has not been any quantitative analysis used for the ToM measures in this case

xii) *Overall reporting*

Well addressed	<ul style="list-style-type: none"> The article covers a majority of the areas recommended by the relevant guideline statement for reporting.
Adequately addressed	<ul style="list-style-type: none"> Although the article does not fully follow the relevant guidance statement, its accessibility for the purposes of this review is not notably limited by omission of areas recommended to be reported.
Limitations	<ul style="list-style-type: none"> Areas recommended to be reported by the relevant guidance statement have been omitted and this has meant that the extraction of relevant information or assessment of areas of quality for the purposes of this review has been limited.
Not reported	<ul style="list-style-type: none"> N/A as apparent from presentation of study.
Not addressed	<ul style="list-style-type: none"> N/A, as above.

7.3 Appendix C – Studies excluded from Systematic Review at Stage 3

Table 7.3.1 Reasons for exclusion of studies during stage 4 of systematic review search strategy.

Reason for exclusion	Study
<i>No theory of mind measure</i>	Aghotor <i>et al.</i> (2010) ⁷⁸ Cherkasova (2012) ⁷⁹ Lindenmayer <i>et al.</i> (2013) ⁸⁰ Moritz & Woodward (2007) ⁸¹ Sacks <i>et al.</i> (2013) ⁸²
<i>Did not report any results</i>	Pijnenborg <i>et al.</i> (2011) ⁸³
<i>Had diagnoses of participants broader than inclusion criteria</i>	Combs <i>et al.</i> (2007) ⁸⁴ Penn <i>et al.</i> (2005) ⁵⁵ Penn <i>et al.</i> (2007) ⁸⁵ Study 2 of Roberts (2007) ⁸⁶ Roberts <i>et al.</i> (2014) ⁸⁷
<i>Duplicates</i>	Adams, 2008 – published in Combs <i>et al.</i> (2007) ⁸⁴ Pilot studies 1 & 2 and Study 1 in Roberts (2007) ⁸⁶ – published in Penn <i>et al.</i> (2005) ⁵⁵ ; Roberts & Penn, (2009) ³⁷ ; and Combs <i>et al.</i> 2007) ⁸⁴ respectively.

7.4 Appendix D - Author guidelines for the Journal of Clinical Psychology

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Abstract. Abstracts are required for research articles, review articles, commentaries, and notes from the field. A structured abstract is required and should be 150 words or less. The headings that are required are:

Objective(s): Succinctly state the reason, aims or hypotheses of the study.

Method (or Design): Describe the sample (including size, gender and average age), setting, and research design of the study.

Results: Succinctly report the results that pertain to the expressed objective(s).

Conclusions: State the important conclusions and implications of the findings.

In addition, for systematic reviews and meta-analyses the following headings can be used,

Context; Objective; Methods (data sources, data extraction); Results; Conclusion. For Clinical reviews: Context; Methods (evidence acquisition); Results (evidence synthesis); Conclusion.

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Final Revised Manuscript . A final version of your accepted manuscript should be submitted electronically, using the instructions for electronic submission detailed above.

Artwork Files . Figures should be provided in separate high-resolution EPS or TIFF files and should not be embedded in a Word document for best quality reproduction in the printed publication. Journal quality reproduction will require gray scale and color files at resolutions yielding approximately 300 ppi. Bitmapped line art should be submitted at resolutions yielding 600-1200 ppi. These resolutions refer to the output size of the file; if you anticipate that your images will be enlarged or reduced, resolutions should be adjusted accordingly. All print reproduction requires files for full-color images to be in a CMYK color space. If possible, ICC or ColorSync profiles of your output device should accompany all digital image submissions. All illustration files should be in TIFF or EPS (with preview) formats. Do not submit native application formats.

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Article Types

- **Research Articles** . Research articles may include quantitative or qualitative investigations, or single-case research. They should contain Introduction, Methods, Results, Discussion, and Conclusion sections conforming to standard scientific reporting style (where appropriate, Results and Discussion may be combined).
- **Review Articles** . Review articles should focus on the clinical implications of theoretical perspectives, diagnostic approaches, or innovative strategies for assessment or treatment. Articles should provide a critical review and interpretation of the literature. Although subdivisions (e.g., introduction, methods, results) are not required, the text should flow smoothly, and be divided logically by topical headings.
- **Commentaries** . Occasionally, the editor will invite one or more individuals to write a commentary on a research report.
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- **News and Notes** . This section offers a vehicle for readers to stay abreast of major awards, grants, training initiatives; research projects; and conferences in clinical psychology. Items for this section should be summarized in 200 words or less. The Editors reserve the right to determine which News and Notes submissions are appropriate for inclusion in the journal.

Editorial Policy

Manuscripts for consideration by the *Journal of Clinical Psychology* must be submitted solely to this journal, and may not have been published in another publication of any type, professional or lay. This policy covers both duplicate and fragmented (piecemeal) publication. Although, on occasion it may be appropriate to publish several reports referring to the same data base, authors should inform the editors at the time of submission about all previously published or submitted reports stemming from the data set, so that the editors can judge if the article represents a new contribution. If the article is accepted for publication in the journal, the article must include a citation to all reports using the same data and methods or the same sample. Upon acceptance of a manuscript for publication, the corresponding author will be required to sign an agreement transferring copyright to the Publisher; copies of the Copyright Transfer form are available from the editorial office. All accepted manuscripts become the property of the Publisher. No material published in the journal may be reproduced or published elsewhere without written permission from the Publisher, who reserves copyright.

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Production Questions:

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Fax: 201-748-8852

E-mail: aelder@wiley.com

7.5 **Appendix E – Details of scoring and interpretation of measures used**

7.5.1 *Scoring of measures*

For each of the measures used in this study, a summary of their scoring and interpretation is provided to aid understanding of how participants' were classified.

7.5.1.1 *History of violence rating*

Participants completed a questionnaire developed by the lead author, which explored their history of violence without seeking any identifiable information about acts of violence, to increase the likelihood of accurate responses being provided. Additionally, participants' case files were reviewed to provide collateral information regarding their known histories of violence. Based on the information obtained, they were rated using the scale outlined in Table 7.6.1. This is a modified version of the 'Rating from previous record' subscale of the Violence Rating Scale (Robertson *et al.*, 1987). It was changed to include all incidents of violence, rather than just those for which participants' had received convictions. Additionally, damage to property was removed, with only violence (including sexual violence) towards others rated. Participants rated as '0' or '1' were counted in a 'low/no history of violence' group, with participants receiving any of the higher scores being classed as having a 'substantial history of violence'.

Table 7.6.1. Modified ‘Rating from previous record’ subscale of the Violence Rating Scale (Robertson *et al.*, 1987)

Rating from previous record	Score
Never violent – never gets into fights	0
Some evidence of violence - occasional fights but nothing more serious than common assault	1
One or two incidents of assault causing actual bodily harm (ABH), or sexual assault resulting in physical and/or psychological harm	2
Three or more incidents of ABH or sexual assault, but no incidents that are as serious as in ‘4’ below	3
One or more severely violent episodes in which someone’s life or health has been seriously endangered, i.e. murder/attempted murder/rape/aggravated sexual assault/grievous bodily harm	4

7.5.1.2 International Personality Disorder Examination Screening Questionnaire (IPDE-SQ) (DSM-IV) (Loranger, 1999)

Participants who scored 3 or above for one or more personality disorder subscales on the IPDE screening tool were classed as *potentially* meeting criteria for these, as per the guidelines of this assessment. For the purposes of analysis, these were classed “Present” for “Potential presence of personality disorder(s)”. Those who did not score 3 or above for any of the personality disorder subscales were classed as “Absent”.

7.5.1.3 Patient Health Questionnaire (PHQ-9) (Spitzer *et al.*, 1999)

Participants who scored 10 or over on the PHQ-9 were classed as falling within a clinically significant range for depression. This cut-off has been determined based on its sensitivity and specificity both being 88% at this score (Kroenke *et al.*, 2001). Participants were therefore categorised as “Depressed” or “Not depressed” based on their score in relation to this cut-off.

7.5.1.4 Autism Spectrum Quotient (AQ-10) (Allison *et al.*, 2012)

Participants who scored over 6 on the AQ10 meet the criteria for further assessment of ASD (Allison *et al.*, 2012). This was classed as “Yes” for “Possible presence of ASD”, with those scoring 6 or below classed as “No”.

7.5.1.5 *Psychosis Evaluation Tool for common Clinical Caregivers (PECC) (Lindström et al., 1997)*

The presence of symptoms of schizophrenia among participants was assessed using the PECC. If a score of 3 or more was assigned on any of the domains assessed for positive symptoms (the lowest score at which the symptom is considered to be present), then a classification of “Present” was used for that “Presence of positive symptomatology”. The same approach was used for negative symptoms, along with anxiety.

7.5.1.6 *Pictures of Facial Affect (PoFA) - Facial Expressions of Emotion: Stimuli and Tests (FEEST) (Young et al., 2002)*

Participants’ performances on overall facial affect recognition, along with recognition of individual emotions, were each classed as either “Normal” or “Impaired” by comparing participants’ scores to the normative data by age provided in the FEEST manual (Young et al., 2002).

7.5.1.7 *Unexpected Transfer Test (Wimmer & Perner, 1983).*

Participants’ performance on this first-order false belief test was classed as “Normal” if they answered the theory of mind question correctly, or “Impaired” if they did not.

7.5.1.8 *Location Change (Ice Cream Van) Task (Perner & Wimmer, 1985)*

Participants’ performance on the second-order theory of mind test was classed as “Normal” if they answered both the theory of mind and the control questions correctly, or “Impaired” if they did not. It is noted that participants classed as “Impaired” may fail to answer the theory of mind question correctly due to a lack of understanding of the story, rather than necessarily due to impaired theory of mind ability; indeed over a third of participants in each group gave an incorrect response on the control questions for at least one of the stories completed.

7.5.1.9 *Faux Pas Recognition Test (Adult Version) (Stone et al., 1998)*

In order to classify participants' performance on the faux pas test as "Normal" or "Impaired", a cut-off point was determined for their detection score. Whilst normative data is not provided with this measure, Gregory *et al.* (2002) recruited 16 "healthy control" participants. Although eight of these were female, this sample is the only adult control that could be identified in the literature for use of this test. The average correct detection of faux pas by controls was 0.95 (SD=0.1), with the mean correct rejection on non-faux pas stories by controls was 0.99 (SD=0.1). Although this was for ten faux pas and ten control stories, rather than five of each as in this study, as it is a ratio score it is comparable. By averaging these scores, an overall correct performance score for controls of 0.97 was established. The standard deviation of the combined correct detection and correct rejection was 0.071. This mean standard deviation was then multiplied by 1.645 and subtracted from 0.97 to provide a cut-off score of 0.853. This was undertaken so that the cut off is 1.645 SD below the average score, which has a significance of $p=0.05$ for a one-tailed normal distribution. Therefore, scores of 85% or below were considered to significantly differ from the performance of controls and so was classed as "Impaired".

7.5.1.10 *Interpersonal Reactivity Index (IRI) (Davis, 1980)*

As the scores on each of the IRI subscales were to be used for correlations, participants' scores were not assigned classifications. These subscales measure discrete components of empathy (Davis, 1983) and as highlighted by D'Orzaio (2004), cannot be summed due to the inverse relationships of some of the scales.

7.5.2 *Dichotomisation of key variables*

Although the dichotomisation of outcomes can be criticised for having lower power to detect an effect, this approach was selected to enable the comparison of more meaningful outcomes. Given the aim of the study was to compare *deficits* between SHV and LNHV groups, it was similarly necessary to identify where deficits *existed*

through comparison with existing normative data for controls. Simple comparison between groups of scores on social cognition measures would not be meaningful without this interpretation.

Included with the FEEST/PoFA is normative data to be used for interpreting an individual's performance as "impaired" or "normal". The comparison of participants' scores to this normative data with resulting classification was necessary to identify where deficits existed. The normative data demonstrated that it is "normal" to make some errors on this test and that the "normal" recognition rate varies by individual emotion. For example, amongst controls only 100% accuracy in the recognition of happiness is "normal", whereas just a 50% accuracy rate is still considered "normal" for recognition of fear. As noted by Demirbuga et al. (2013), a lack of comparison to performance by healthy controls would be a limitation. Without this, it is not possible to determine if a lower recognition rate for a particular emotion is due to a facial affect recognition deficit for the population under study, or due to recognition of that emotion being globally experienced as more challenging.

The questions testing theory of mind ability on the first- and second- order false belief tests used can either be answered correctly or incorrectly; therefore a dichotomous outcome is unavoidable.

For the Faux Pas detection test, although comparison between groups of overall faux pas detection scores as a continuous variable could have been undertaken, it was similarly considered more meaningful to identify where deficits existed in comparison to the faux pas detection ability of healthy controls, thus placing the performance of each group in context. Classification of performance on this test as a dichotomous outcome had the additional benefit of enabling consistency of outcomes across measures. When planning the study, this consistency was considered important to enable a regression to be undertaken (were sufficient

participants recruited), with a participant's performance planned to be coded on a scale of 0-3 (as outlined in section 4.3.2 (Analysis B) of the supplementary methods chapter). This was planned as each assessment had been considered to be of increasing difficulty given the ages at which each ability had been found to develop in controls (Muris et al., 1999).

7.6 Appendix F – Ethical and R&D approvals

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18 March 2013

Miss Heather Langham
Department of Clinical Psychology
The University of Edinburgh
Medical School
Teviot Place
Edinburgh
EH8 9AG

Dear Miss Langham,

Study title: Social cognition deficits and violence in people with a
diagnosis of schizophrenia.
REC reference: 13/SS/0021
IRAS project ID: 112986

Thank you for your letter of 18 March 2013, responding to the Committee's request for further information on the above research.

The further information was considered in correspondence by a sub-committee of the REC.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Joyce Clearie: joyce.clearie@nhslotthian.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.



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Chair Dr Charles J Winstanley
Chief Executive Tim Davison
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Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity. Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		04 February 2013
Covering Letter		17 March 2013
Investigator CV	Langham	21 January 2013
Investigator CV	O'Rourke	27 January 2013
Other: Modified Violence rating scale		27 January 2013
Other: NHS Lothian: Letter to inform HCT and GP	2	17 March 2013
Other: TSH: Letter to inform HCT and GP	2	17 March 2013
Participant Consent Form: For contact and clarifying info for potential participants	2.0	17 March 2013
Participant Consent Form: For participation in the study non site specific	4	17 March 2013
Participant Information Sheet: NHS Lothian A4 version for computer reference	6	17 March 2013
Participant Information Sheet: NHS Lothian A5 version for printing	6	17 March 2013
Participant Information Sheet: TSH A4 version for computer reference	6	17 March 2013
Participant Information Sheet: TSH A5 version for printing	6	17 March 2013
Protocol	4	04 February 2013
Questionnaire: Patient Health Q		
Questionnaire: Interpersonal Reactivity Index		
Questionnaire: Q regarding use of violence	2	27 January 2013
Questionnaire: Unexpected transfer test		21 January 2013
Questionnaire: Location Change Task		21 January 2013
Questionnaire: Excerpt from Faux pas recognition test Adult version		21 January 2013
REC application		04 February 2013
Referees or other scientific critique report		05 December 2012
Response to Request for Further Information		18 March 2013
Summary/Synopsis	Patient involvement - where identified by staff	04 February 2013

Summary/Synopsis	where patient makes direct contact	04 February 2013
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Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- 7.1.8 Notifying substantial amendments
- 7.1.8 Adding new sites and investigators
- 7.1.8 Notification of serious breaches of the protocol
- 7.1.8 Progress and safety reports
- 7.1.8 Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/SS/0021	Please quote this number on all correspondence
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We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely,



Mr Thomas Russell
Chair

Email: alex.bailey@nhslothian.scot.nhs.uk

"After ethical review – guidance for researchers"

Copy to:

Mr Jamie Pitcairn

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 465 5789

www.nhsllothian.scot.nhs.uk

Date 02 September 2013
Your Ref
Our Ref

Enquiries to: Joyce Clearie
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Email: Joyce.Clearie@nhsllothian.scot.nhs.uk

02 September 2013

Miss Heather Langham
Trainee Clinical Psychologist
The State Hospital
Department of Clinical Psychology, The University of Edinburgh
Medical School, Teviot Place
Edinburgh
EH8 9AG

Dear Miss Langham

Study title: Social cognition deficits and violence in people with a diagnosis of schizophrenia.
REC reference: 13/SS/0021
Protocol number: N/A
Amendment number:
Amendment date: 07 August 2013
IRAS project ID: 112986

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved were:

Document	Version	Date
Protocol	5	01 September 2013
Changes to Protocol document	1	06 August 2013



Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston
Chief Executive Tim Davison
Lothian NHS Board is the common name of Lothian Health Board

Notice of Substantial Amendment (non-CTIMPs)	07 August 2013
Questionnaire: AQ10	01 May 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/SS/0021:	Please quote this number on all correspondence
--------------------	---

Yours sincerely



Mr Thomas Russell
Chair

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mr Jamie Pitcaim, The State Hospital
Mr Jamie Pitcaim*

South East Scotland Research Ethics Committee 02

Attendance at Sub-Committee of the REC meeting on August 2013

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Thomas Russell	Retired Consultant Neurosurgeon	Expert
Professor Lindsay Sawyer	University Lecturer	Lay

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Alex Bailey	Scientific Officer
Ms Joyce Clearie	Coordinator

Heather Langham
Trainee Clinical Psychologist
The State Hospital

Wednesday the 5th of December 2012

Dear Heather,

Re: Research Study: Social cognition deficits and violence in people with a diagnosis of schizophrenia.

Many thanks for your revised research proposal that was reviewed by the TSH Research Committee on Thursday 29th of November 2012. The committee found the proposal to be an interesting piece of work, and felt that you had addressed the concerns noted within the committee's original feedback. Subsequently the committee were happy to approve the study. This letter will be copied to the Associate Medical Director along with evidence of your ethical approval (once received), who will subsequently provide final management approval for the study to take place within TSH.

The research committees' approval is conditional on your providing the committee with regular 6-monthly progress reports (Initial progress report due to be submitted to the May 2013 Research Committee meeting), and a final study report with a focus on how to implement your research findings in practice. This is an important mechanism by which the committee track progress, and is also a key component of our research governance processes.

If you require any further assistance, or have any feedback on the Research approval process then please do not hesitate to contact me.

Yours sincerely



JAMIE PITCAIRN
Research & Development Manager
The State Hospital

University Hospitals Division

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

FM/SS/approval

21 March 2013

Miss Heather Langham
The State Hospital
The University of Edinburgh
Teviot Place
Edinburgh
EH8 9AG

Dear Miss Langham



Research & Development
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343

Email: R&DOffice@luht.scot.nhs.uk

Director: Professor David E Newby

Lothian R&D Project No: 2013/P/PSY/07

Title of Research: Social cognition deficits and violence in people with a diagnosis of schizophrenia

REC No: 13/SS/0021

Patient Information Sheet: Version 6
dated 17 March 2013

Consent Form: Version 4 dated 17 March 2012
Consent Form (Care Team to share information with CI):
Version 2 dated 17 March 2013

Protocol: Version 4 dated 04 February 2013

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian. This includes any changes made subsequent to management approval and prior to favourable opinion from the REC

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study

Yours sincerely

Fiona McArdle

Ms Fiona McArdle
Deputy R&D Director

Cc Paul Deane, QA Manager
Pamela Shand, NRS

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

KM/LM

28 September 2013

Miss Heather Langham
The State Hospital
The University of Edinburgh
Edinburgh

RESEARCH & DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@nhslothian.scot.nhs.uk

Director:
Professor David E Newby

Dear Miss Langham

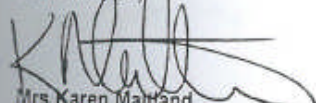
REC No:	13/SS/0021
R&D Project ID No:	2013/P/PSY/07
Amendment:	Substantial amendment No.1 dated 7 August 2013
Title of Research	Social cognition deficits and violence in people with a diagnosis of schizophrenia

I am writing in reply to recent correspondence in relation to an amendment(s) to the above project and the subsequent updated documents as follows.

- o Protocol – Version 5 dated September 2013
- o Changes to Protocol Document – Version 1 dated 6 August 2013
- o AQ-10 Questionnaire – dated 1 May 2012

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated.

Yours sincerely



Mrs Karen Maitland
Research Governance Manager

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

SS/TW

2 December 2013

Miss Heather Langham
The State Hospital
The University of Edinburgh
Edinburgh

RESEARCH & DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@nhslothian.scot.nhs.uk

Director:
Professor David E Newby

Dear Miss Langham

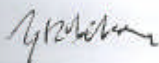
REC No:	13/SS/0021
R&D Project ID No:	2013/P/PSY/07
Amendment:	Minor amendment dated 22 November 2013
Title of Research	Social cognition deficits and violence in people with a diagnosis of schizophrenia

I am writing in reply to recent correspondence in relation to an amendment to the above project as follows.

- Addition of two new sites within Lothian - St Johns Hospital and Royal Edinburgh Hospital.

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated.

Yours sincerely

pp 

Mrs Susan Shepherd
Head of Research Governance

Date: 15 Jan 2014
Your Ref:
Our Ref:
Direct Line: 01324 677564
Email: @nhs.net
R&D ref: FV750

Miss Heather Langham
Department of Clinical Psychology
The University of Edinburgh
Medical School
Teviot Place
Edinburgh
EH8 9AG

Dear Miss Langham,

Study title: Social cognition deficits and violence in people with a diagnosis of schizophrenia.

REC reference: 13/SS/0021

Following the favourable opinion from the South East Scotland Research Ethics Committee 02 on 18 March 2013, I am pleased to confirm that I formally gave Management Approval to the study above on 15 January 2014


This approval is granted subject to your compliance with the following:

1. Any amendments to the protocol or research team must have Ethics Committee and R&D approval (as well as approval from any other relevant regulatory organisation) before they can be implemented. Please ensure that the R&D Office and (where appropriate) NRS are informed of any amendments as soon as you become aware of them.
2. You and any local Principal Investigator are responsible for ensuring that all members of the research team have the appropriate experience and training, including GCP training if required.
3. All those involved in the project will be required to work within accepted guidelines of health and safety and data protection principles, any other relevant statutory legislation, the Research Governance Framework for Health and Community Care and IHC-GCP guidelines. A copy of the Framework can be accessed via the Chief Scientist Office website at: <http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf> and ICH-GCP guidelines may be found at <http://www.ich.org/LOB/media/MEDIA482.pdf>
4. As custodian of the information collected during this project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT security policies, until the destruction of this data.
5. You or the local Principal Investigator will be required to provide the following reports and information during the course of your study:
 - A progress report **annually**

- Recruitment numbers on a **monthly** basis (if your study should be added to the NIHR research Portfolio you will receive a separate letter from the R&D Office detailing the steps to be taken)
- Report on SAEs and SUSARs if your study is a Clinical Trial of an Investigational Medicinal Product
- Any information required for the purpose of internal or external audit and monitoring
- Copies of any external monitoring reports
- Notification of the end of recruitment and the end of the study
- A copy of the final report, when available.
- Copies of or full citations for any publications or abstracts

The appropriate forms will be provided to you by the Research and Development office when they are needed. Other information may be required from time to time.

Yours sincerely


DR. PETER MURDOCH
 Interim Medical Director

CC: nhsg.NRSPCC@nhs.net

suzanne.o'rourke@ed.ac.uk

NHS Borders

Research Administration
Clinical Governance & Quality

Clinical Governance &
Quality
Borders General Hospital
Melrose
Roxburghshire TD6 9BS



Telephone 01896 826719
Fax 01896 826040
www.nhsborders.org.uk

Miss Heather Langham
The State Hospital
Carstairs
Lanark
ML11 8RP

Date 01 August 2014
Our Ref 13/BORD/19

Enquiries to Joy Borowska
Extension 01896 826717
Email research.governance@borders.scot.nhs.uk

Dear Miss Langham

NRS13/MH94: Social cognition deficits and violence in people with a diagnosis of schizophrenia

Thank you for sending details of your study to NHS Borders. I can confirm that the Research Governance Committee has reviewed the documentation, and on this basis I am pleased to inform you that this study has management approval for commencement within NHS Borders.

It is a condition of approval that everyone involved in this study abides by the guidelines/protocols implemented by NHS Borders with respect to confidentiality and Research Governance. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek advice if you are unsure.

Please advise the R&D Office immediately of any changes to the project such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Borders. Please also advise the R&D office when recruitment has been completed and when the study has been fully completed.

Amendments to the protocol will require approval from the ethics committee that approved your study. The R&D approval must also be sought for amendments.

May I take this opportunity to wish you every success with your project? Please do not hesitate to contact the R&D Office should you require any further assistance.

Yours sincerely

A handwritten signature in dark ink that reads 'Thomas Cripps'. The signature is written in a cursive style with a large 'T' and a long, sweeping underline.

Thomas Cripps
Associate Medical Director (Clinical Governance)

CC NRSPCC

NHS Borders

Human Resources Department

Human Resources Department
Borders General Hospital
Melrose
Roxburghshire
TD6 9BS

Telephone: 01896 826151
Fax: 01896 826159

www.nhsborders.org.uk

Date Thursday, 30 January 2014
Our Ref CH/RW

Enquiries to Colin Herbert, Head of HR
Direct Line 01896 826170
Email colin.herbert@borders.scot.nhs.uk

PERSONAL

Heather Langham
Trainee Clinical Psychologist
The State Hospital
Carstairs
LANARK
ML11 8RP

Dear Heather

Re: Letter of access for research

This letter confirms your right of access to conduct research through NHS Borders for the purpose and on the terms and conditions set out below. This right of access commenced on 27 January 2014 and ends on 26 September 2014 unless terminated earlier in accordance with the clauses below.

The information supplied about your role in research at The State Hospital has been reviewed and you do not require an honorary research contract with NHS Borders. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to NHS Borders premises. You are not entitled to any form of payment or access to other benefits provided by NHS Borders to employees and this letter does not give rise to any other relationship between you and NHS Borders, in particular that of an employee.

While undertaking research through NHS Borders, you will remain accountable to your employer, The State Hospital, but you are required to follow the reasonable instructions of Mike Henderson, Clinical Psychologist, in NHS Borders or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by NHS Borders in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Borders policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Borders in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Borders premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises



as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that NHS Borders accepts no responsibility for damage to or loss of personal property.

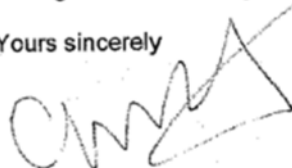
We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of NHS Borders or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Borders will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in NHS Borders.

On your first day of arrival within NHS Borders you will be required to visit the R&D Office within the Clinical Governance Support Team Office on the 1st floor of Borders General Hospital, Melrose. You will be required to bring both your letter of access/honorary contract along with photographic identification from your host organisation. When these have been reviewed you will be issued with a visiting researcher badge which will allow you access to the required areas.

Yours sincerely



Colin Herbert
Head of HR, NHS Borders

cc: Mike Henderson
HR department, The State Hospital

